

As filed with the Securities and Exchange Commission on _____, 2014

Registration No.
333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM F-1

REGISTRATION STATEMENT UNDER
THE SECURITIES ACT OF 1933

FORWARD PHARMA A/S

(Exact Name of Registrant as Specified in its Charter)

Denmark <i>(State or Other Jurisdiction of Incorporation or Organization)</i>	2834 <i>(Primary Standard Industrial Classification Code Number)</i>	Not Applicable <i>(I.R.S. Employer Identification No.)</i>
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Approximate date of commencement of proposed sale to the public: As soon as practicable after effectiveness of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price⁽¹⁾⁽²⁾	Amount of registration fee
Ordinary shares, par value DKK 1.00 per share	\$	\$

(1) Includes ordinary shares that may be purchased by the underwriters pursuant to an option to purchase additional ordinary shares to cover over-allotments.

(2) Estimated solely for the purpose of calculating the registration fee pursuant to rule 457(c) of the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this Prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This Prospectus is not an offer to sell these securities, and we are not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to completion, dated April 8, 2014

Prospectus

ordinary shares

Forward Pharma A/S



This is an initial public offering of ordinary shares by Forward Pharma A/S. We are selling _____ of our ordinary shares. We currently expect the initial public offering price to be between \$ _____ and \$ _____ per ordinary share. Currently, no public market exists for our ordinary shares.

We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol "FWP."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

	Per share	Total
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____
Proceeds to us, before expenses	\$ _____	\$ _____

We have granted the underwriters an option for a period of 30 days to purchase up to an additional _____ of our ordinary shares to cover over-allotments.

Delivery of the ordinary shares will be made on or about _____, 2014.

Investing in our ordinary shares involves a high degree of risk. See "Risk Factors" beginning on page 10.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this Prospectus. Any representation to the contrary is a criminal offense.

Leerink Partners

_____, 2014

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Unless otherwise indicated or the context otherwise requires, all references in this Prospectus to “Forward Pharma A/S” refer to Forward Pharma A/S, and all references to “Forward Pharma,” the “Company,” “we,” “our,” “ours,” “us” or similar terms refer to Forward Pharma A/S and its subsidiary.

We have not authorized anyone to provide any information or to make any representations other than that contained in this Prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the underwriters (i) have authorized any other person to provide you with different or additional information, or (ii) are making an offer to sell the ordinary shares in any state or other jurisdiction where the offer or sale is not permitted. This offering is being made in the United States and elsewhere solely on the basis of the information contained in this Prospectus. You should assume that the information appearing in this Prospectus is accurate only as of the date on the front cover of this Prospectus, regardless of the time of delivery of this Prospectus or any sale of the ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this Prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this Prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire Prospectus carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our consolidated financial statements, including the notes thereto, included in this Prospectus, before deciding to invest in our ordinary shares.

Our company

Forward Pharma is a Danish biopharmaceutical company preparing to initiate a Phase 3 clinical trial using FP187, a proprietary formulation of dimethyl fumarate, or DMF, for the treatment of multiple sclerosis, or MS, patients. Since our founding in 2005, we have worked to advance unique formulations of DMF, an immune modulator, as a therapeutic to improve the health and well-being of patients with immune disorders including MS. FP187, our clinical candidate, is a DMF formulation in an oral dose that employs both matrix and delayed release technologies to control drug release which we plan to advance for the treatment of relapsing remitting MS, or RRMS, and other immune disorders, such as psoriasis.

Our focus on Dimethyl Fumarate, or DMF

Oral drugs employing DMF as an active pharmaceutical ingredient, or API, have been in use for over half a century. Today, DMF is the API found in Tecfidera®, which Biogen Idec Inc., or Biogen, began selling for the treatment of RRMS following approval by the U.S. Food and Drug Administration, or FDA, in March 2013 (and approval by the European Commission, or EC, in February 2014). Tecfidera®, which is an oral dose of 480 mg of DMF daily (240 mg twice daily), generated global sales from launch in April 2013 through the end of 2013 of \$876 million. DMF is also an API found in Fumaderm®, which has been sold for the treatment of psoriasis since 1994.

In 2004, a private Swedish company Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech General Partners ApS (an affiliate of one of our largest shareholders), assessed the potential for DMF to become a significant global product. Aditech specifically focused on the development of an innovative delayed and controlled release formulation of DMF, with the goal of limiting side effects typically associated with DMF treatment.

We were founded in 2005 for the purpose of exploiting a patent family Aditech filed relating to, among other things, its delayed and controlled release formulation for DMF, and in 2010 we acquired this patent family from Aditech. Under our agreements with Aditech, we obtained, among other things, Aditech’s patents and associated know-how related to DMF formulations. For more, see “Related Party Transactions – Aditech Agreement.”

The patent family that we acquired from Aditech included an international patent application filed in 2005, disclosing, among other things, formulations of DMF that provide for its controlled release in the small intestine, where we believe that DMF has its immunomodulatory impact. This international application became the basis for a family of national patent applications which subsequently were filed relating to DMF. Two European patents, one from the original Aditech patent family and one from a patent family of ours (involving erosion matrix formulations of DMF with a thin enteric coating) have been granted and both are now the subject of opposition proceedings. In the U.S., two of our patent applications have been found allowable. One of those applications claims particular up-titration schedules of using DMF to treat MS, while the other claims to treat MS using particular compositions containing DMF and that also specify levels of a DMF metabolite called mono methyl fumarate, or MMF, in the bloodstream. In a third application, the Examiner has found our claims directed to methods of treating MS using a 480 mg dose of DMF to be allowable and has recommended that an interference be declared against Biogen’s U.S. Patent No. 8,399,514.

In order to assess FP187’s safety profile for human use, we have performed 28 pre-clinical studies on DMF since 2006, gathering data through animal testing (and in certain cases *in vitro* testing of DMF in cells) on its pharmacological activity, toxicity profile, and on dosing level effects. Beginning in 2007, we commenced a set of Phase 1 clinical trials followed by a Phase 2 clinical trial to investigate, among other things, safety and dosing tolerability of FP187. We have successfully completed all of these clinical studies, collectively involving over 300 psoriasis patients and healthy volunteers, and gathering substantial positive safety and dosing data.

To advance FP187 for use as a drug to treat RRMS in the U.S., in August 2013 we held a pre-Investigational New Drug, or IND, Application meeting with the FDA. Prior to this pre-IND meeting, we submitted a briefing book to the FDA, which included our high-level description of a proposed 48-week Phase 3 trial, which we expect will include up to 2,000 subjects. The primary and key secondary efficacy endpoints, respectively, for the proposed Phase 3 trial will be annual relapse rate, or ARR, and a favorable change in the sustained accumulation of disability, or SAD, in each case for RRMS patients. Our pre-IND meeting submission noted that we intend to compare FP187 to an active beta interferon, or IFN β , comparator drug. We expect to file our IND for RRMS by the end of April 2014 and to submit the protocol for our Phase 3 study in the third quarter of 2014.

Following completion of our planned Phase 3 trial, we intend to submit to the FDA our New Drug Application, or NDA, for FP187 to treat RRMS. Approval by the FDA of an NDA is dependent on a number of factors. A final decision as to whether the program we shared with the FDA in advance of our pre-IND meeting is sufficient to support approval (including the sufficiency of our proposed single Phase 3 trial and whether a favorable change in SAD will need to be demonstrated by us at the time of our NDA submission) can only be made by the FDA once it has reviewed our full NDA, including the data from our Phase 3 study. We expect that patient enrollment for the Phase 3 trial we are contemplating will take at least 18 months, with completion of the final patient's initial 48-week treatment period after a total of 30 months. When the last patient dosed has completed the 48-week treatment period, we expect that we will have a substantial number of patients with two years of data, which we believe will allow us to complete an analysis of the effects of FP187 on SAD which can be provided to the FDA when we submit our NDA. As a result, we believe that any requirement by the FDA for data on SAD will not delay a decision on whether to approve FP187 for the treatment of RRMS.

We intend to submit our NDA for FP187 to treat RRMS under Section 505(b)(1) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDC Act, based on pre-clinical and clinical data we have and will have developed and independently own. Section 505(b)(1) of the FDC Act prescribes how a product may be submitted for approval by the FDA as a new drug based on clinical trial data and other information independently developed and owned by the party making the NDA submission, or obtained from a third-party with a right of reference.

In Europe, we have held preliminary discussions concerning marketing authorization for FP187 with the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) in Germany, and more recently in November 2013 held a scientific consultation with the European Medicines Agency, or EMA. We expect to apply for a European Union, or EU, marketing authorization for FP187 to treat RRMS.

We also intend to pursue the development of FP187 for the treatment of psoriasis, and expect to commence a Phase 3 clinical trial program for psoriasis beginning in 2014.

History of DMF

A German pharmacist discovered in the late 1950s that fumaric acid derivatives were useful for the treatment of psoriasis. Over the following years, various blends of fumaric acid derivatives, including DMF, were tested and used in different doses throughout Germany and, later, in other parts of Europe. Pharmacies in Germany often made their own compounded versions for the treatment of psoriasis.

In 1994, Fumapharm AG (acquired by Biogen in 2006) received approval in Germany to market Fumaderm®, which contains DMF and three ethyl fumaric ester salts, for the treatment of psoriasis. DMF is also the sole API in Biogen's Tecfidera®. Fumaderm® has not been approved outside of Germany, but it is nonetheless available throughout Europe as a prescription drug sourced from German pharmacies. Tecfidera® is sold in both the U.S. and Europe. We estimate that there have been well over 150,000 patient years of exposure to drugs containing DMF.

Our intellectual property

We divide our intellectual property portfolios primarily into two basic patent families, which we refer to as our "Core Composition Patent" family and our "Erosion Matrix Patent" family. Our Core Composition Patent family, based on international application PCT/DK2005/000648, filed by Aditech in 2005, discloses a broad range of controlled release pharmaceutical compositions of DMF as well as the use of a dose of about 480 mg of DMF per day to treat MS. Our Erosion Matrix Patent family, based on international application PCT/EP2010/050172, filed in 2010, discloses our delayed and controlled release formulations of DMF in FP187.

Core Composition Patent Family

In the EU, a patent from our Core Composition Patent family, EP2316430, has been granted. EP2316430 covers DMF formulations with certain in vitro dissolution profiles. In the U.S., U.S. Application Nos. 13/957,117 and 13/957,220 have been allowed.

U.S. Application No. 13/957,117 claims the use of delayed release formulations of DMF to treat MS according to an up-titration schedule that reaches a total daily dose of about 480 mg. U.S. Application No. 13/957,220 claims a method of treating an MS subject with about 480 mg of DMF per day, using delayed release formulations containing from about 120 mg to 240 mg of DMF which, following administration, result in certain levels of MMF in the bloodstream.

Two third-party pre-issuance submissions have recently been filed with the USPTO, questioning the patentability of the claims in each of the two U.S. patent applications from our Core Composition Patent family that have been allowed. We have filed a response to the third-party pre-issuance submission in Application No. 13/957,117 and are prepared to do so in Application No. 13/957,220. We believe the third-party submissions are defective and, even if they are considered by the USPTO, expect both of our patent applications to be issued as patents.

We were recently informed by the USPTO Examiner that she believes the claims in another of our patent applications in the Core Composition Patent family, U.S. Application No. 11/576,871, to be allowable and in consultation with her supervisor and a patent interference specialist, has recommended both that an interference be declared against Biogen's U.S. Patent No. 8,399,514, whose claims also cover a method of treating MS using about a 480 mg daily dose of DMF, and that we be designated as the so-called senior party.

The USPTO website indicates that the Examiner has prepared a memorandum in support of an interference, which will be reviewed by an administrative patent judge. Such interference, if declared, will give us the opportunity to prove to the USPTO that we were the first to invent the method of treating MS using about a 480 mg daily dose of DMF.

Multiple third parties, including Biogen, are opposing our patent EP2316430 (covering DMF formulations) before the European Patent Office, or EPO. In view of the publication of WO2006/037342, the international application in the Core Composition Patent Family, on April 13, 2006, prior to Biogen's February 8, 2007 filing on the use of the 480 mg daily dose to treat MS, we (along with multiple other parties) have filed an opposition against Biogen's EP2137537 B1 patent which has claims that cover this dosing regimen.

Erosion Matrix Patent family

In the EU, a patent from our Erosion Matrix Patent family, EP2379063 (covering matrix formulations with a thin enteric coating), has been granted. Multiple third parties, including Biogen, are opposing this patent before the EPO. The U.S. counterpart, U.S. Application No. 13/143,498, was allowed by the USPTO but withdrawn from allowance to permit the USPTO Examiner to consider the opposition papers in EP2379063.

Other patent families

Beyond our Core Composition Patent and Erosion Matrix Patent families, our other patent families include pending applications in the EU and the U.S., mainly directed to new dosing regimens of DMF. We believe that our overall patent portfolio, when mature, will position FP187 competitively in the key markets of the U.S. and the EU.

Our business strategy

We have focused on DMF's potential as an immune-modulating drug to improve the health and well-being of patients with immune disorders for approximately the past 10 years, during which time we have assembled and continue to develop our intellectual property portfolio and regulatory strategy. We believe our intellectual property portfolio, combined with the clinical data we have and will have independently obtained and the discussions we have had with the FDA, BfArM and EMA, provide us with the opportunity to pursue the development of FP187 for the treatment of RRMS in the U.S. and the EU. We intend to use the net proceeds from this offering to, among other things, pursue a Phase 3 clinical trial of FP187 for the treatment of RRMS which we believe, if successful, would (in combination with other data on FP187 we have and are obtaining) allow us to submit an NDA in the U.S. and a separate marketing authorization application in the EU for FP187 to treat RRMS. We intend to also pursue the development of FP187 for the treatment of psoriasis, including commencing a Phase 3 clinical trial program beginning in 2014.

Components of our business strategy include:

- **Successfully develop FP187 for the treatment of Relapsing Remitting Multiple Sclerosis.** We plan to pursue approval from the FDA and the EC of FP187 for the treatment of RRMS. We believe that, if approved, FP187 could become an important therapeutic in the multi-billion dollar MS drug market.
- **Develop FP187 for the treatment of psoriasis.** We plan to pursue FP187 for the treatment of psoriasis. We believe that, if approved, FP187 could become a compelling treatment option for patients with psoriasis.
- **Exploit and defend our intellectual property rights.** We believe our patents and patent applications related to, among other things, our proprietary formulation technology, combined with our patents and patent applications claiming dosing levels of DMF, are critical assets of our company. We intend to exploit our intellectual property by continuing to pursue our patent applications, and to defend our patent rights as we deem necessary for our business.
- **Obtain marketing exclusivity in the U.S. and the EU for FP187.** In addition to patent protection, if and when an NDA is approved, we will be entitled to up to three and one-half years of marketing exclusivity against generic versions of FP187 in the U.S. In the EU, we will be entitled to up to 11 years of exclusivity from the first date of authorization in the EU.
- **Potentially partner FP187 with third parties.** We may opportunistically seek commercial partners for FP187 to offset risk and preserve capital, if appropriate, although we intend to retain key development and commercialization rights. We believe retaining this strategic flexibility will help us to maximize shareholder value.
- **Continue to explore, and potentially develop, FP187 and other DMF-related formulations for the treatment of other immune disorders.** We intend to continue to explore and potentially develop FP187 and other DMF-related formulations for the treatment of other immune disorder indications, if we determine that such development could be commercially viable.

Mode of Action of DMF and our proprietary formulation

Mode of action

While the exact mode of action of DMF is not fully understood, we believe that some of its therapeutic effects are mediated via modulation of the immune system. From studying immune cells in vitro we believe that DMF can rapidly form adducts by combining with the antioxidant molecule glutathione, or GSH, leading to the functional depletion of GSH, followed by the modulation of various cellular pathways. We believe that one important downstream event of intracellular GSH depletion is the increased expression of the anti-inflammatory stress protein HO-1, with subsequent induction of type II dendritic cells leading to a reduction of inflammatory responses. We also believe that the depletion of GSH can induce apoptosis or cell death in different cell types including activated T cells, reducing inflammatory responses. Other pre-clinical data, we believe, have indicated that DMF can also protect cells, including neuronal cells, against oxidative stress.

In animal models, GSH/DMF adducts have been found in the gastrointestinal mucosa and in the portal vein blood, but not in organs like the heart, brain and liver, which suggests to us that the clinical effects of DMF may be mediated at least in part by DMF exerting its action within the tissues in the intestine or pre-systemic circulation. Such a mode of action of DMF is also supported, we believe, by the fact that DMF has not been directly detected in the bloodstream.

Some proportion of DMF is thought by us to be metabolized by esterases (enzymes ubiquitous in the gastrointestinal, or GI, tract) to produce MMF. In contrast to DMF, MMF can be measured in the bloodstream, but the extent to which it may contribute to clinical efficacy is currently unclear to us. However, recent pre-clinical research suggests to us that sudden plasma peaks of MMF may contribute to the side effect of flushing via interaction with nicotinic acid receptors.

Formulation and clinical profile of FP187

Our proprietary DMF formulation, FP187, employs two strategies which we believe improve the release of DMF by reducing the peaks of MMF in the bloodstream while maintaining overall DMF exposure levels, which, in turn, may control DMF's side effects. FP187 uses an enteric coating material, which forms a polymeric barrier around each DMF-containing core tablet for the purpose of inhibiting the release of DMF in the stomach and allowing for release in the small intestine. In addition, the DMF in FP187 is formulated as an erosion matrix, resulting in what we believe to be a controlled release of DMF in the small intestine after the enteric coating has dissolved. The enteric coating employed by FP187 is thinner than the coating used by the other DMF products, which we believe results in earlier release of DMF in the small intestine.

We think that products containing DMF that lack an erosion matrix formulation (such as Tecfidera® and Fumaderm®) may result in DMF being released in a more concentrated and immediate burst. We believe that the slow rate of release of DMF permitted by FP187's erosion matrix formulation greatly reduces, or even eliminates, the peaks of MMF in the bloodstream observed with formulations in which the DMF is not incorporated into a controlled release matrix, while ensuring that a therapeutically effective dose of DMF is administered, potentially producing fewer and less severe flushing episodes. In addition, we believe that the controlled release of DMF from the erosion matrix formulation, together with the earlier start of release in the small intestine, may allow absorption of DMF over a larger area of GI mucosa, potentially leading to lower local GI concentrations and therefore, we believe, less GI specific side effects.

Risks associated with our business

We are a late clinical-stage biopharmaceutical company, and our business is subject to a number of risks of which you should be aware before making an investment decision. These risks, which are discussed more fully in the "Risk Factors" section of this Prospectus, include:

- We have no products approved for commercial sale, and we have not received regulatory approval for, nor have we generated commercial revenue from, our sole clinical candidate, FP187.
- FP187 is in pre-clinical and clinical development, and clinical trials of FP187 and other studies required for marketing approvals may not be successful. Our planned clinical trials may not be considered sufficient to support marketing authorization appropriately. If we are unable to obtain marketing approvals for, or successfully commercialize, FP187, our ability to generate revenue will be materially impaired.
- Completion of required clinical trials may take longer than we anticipate, which could result in increased costs, limit our access to funding and delay or limit our ability to obtain regulatory approval for FP187. FP187 may not receive the regulatory approvals we plan to seek in a timely manner, or at all.
- We may be unable to obtain, maintain, and exploit the protection of our intellectual property assets, which could harm our ability to compete and impair our business.
- We could be involved in costly litigation or other legal proceedings with respect to our intellectual property.
- Third-party patents, including those of Biogen, may have an adverse effect on our business.
- Our ability to continue as a going concern is dependent on our ability to raise additional capital to fund the advancement of FP187, and if we are unable to successfully raise sufficient additional capital, through future equity or debt financings or through strategic and collaborative ventures with third parties, we will not have sufficient cash flows and liquidity to fund our planned business operations.

- We may require substantial additional funding beyond the net proceeds from this offering to continue and complete the development and commercialization of FP187 and/or exploit or defend our intellectual property.
- We have a history of operating losses and anticipate that we will continue to incur losses for the foreseeable future. As of December 31, 2013, we had an accumulated deficit of \$53.1 million.
- Should we raise additional funds through the sale of equity or convertible debt securities, such funding may cause substantial dilution to our shareholders.
- We have not commercialized FP187 and, even if approved, it may not be reimbursed by governmental authorities, health insurers and other third-party payors at acceptable levels.

Implications of being an emerging growth company

We qualify as an “emerging growth company” as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- the ability to include only two years of audited financial statements and only two years of related management’s discussion and analysis of financial condition and results of operations disclosure;
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002; and
- the ability to provide less disclosure on compensation than is required otherwise under the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our ordinary shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period.

Corporate information

We are a Danish public limited liability company. Our principal executive offices are located at Østergade 24A, 1, 1100 Copenhagen K, Denmark. Our telephone number at this address is +45 33 44 42 42.

Our website address is www.forward-pharma.com. We do not incorporate the information on, or accessible through, our website into this Prospectus, and any information on, or accessible through, our website is not part of this Prospectus.

Investors should contact us for any inquiries at the address and telephone number of our principal executive offices.

THE OFFERING

Ordinary shares offered by us	ordinary shares.
Ordinary shares to be outstanding immediately after this offering	ordinary shares.
Over-allotment option	We have granted the underwriters the right to purchase up to an additional ordinary shares from us within 30 days of the date of this Prospectus, to cover over-allotments, if any, in connection with the offering.
Use of proceeds	<p>We estimate that the net proceeds to us from the offering will be approximately \$, or approximately \$ million if the underwriters' over-allotment option is exercised in full, based on an assumed initial public offering price of \$ per ordinary share, the midpoint of the price range set forth on the cover page of this Prospectus after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently expect that we will use the net proceeds from this offering, together with a bridge financing we expect to enter into which may be convertible into or exchangeable for our equity securities, and our cash and cash equivalents on hand, as follows:</p> <ul style="list-style-type: none">• approximately \$90.0 million for the clinical development of FP187 for the treatment of RRMS;• approximately \$30.0 million for the clinical development of FP187 for the treatment of psoriasis;• approximately \$25.0 million to fund the exploitation and protection of our intellectual property rights (including in connection with oppositions and interference cases); and• the remainder for working capital and other general corporate purposes, including execution of our pre-clinical program. See "Use of Proceeds."
Dividend policy	We have never paid or declared any cash dividends on our shares, and we do not anticipate paying any cash dividends on our shares in the foreseeable future.
Risk factors	See "Risk Factors" and the other information included in this Prospectus for a discussion of factors you should carefully consider before deciding to invest in our ordinary shares.
Listing	We intend to apply to have our ordinary shares listed on the NASDAQ Global Market, or NASDAQ, under the symbol "FWP."

The number of our ordinary shares to be outstanding immediately after this offering is based on 1,736,540 of our Class A shares and 56,851 Class B shares outstanding as of March 31, 2014 and assumes:

- the automatic conversion of all of our Class A and Class B shares into an aggregate of _____ ordinary shares prior to the consummation of this offering pursuant to our framework agreement as described under “Related Party Transactions – Framework Agreement,” which we refer to as the Share Conversion (after which we will only have one class of shares, termed ordinary shares);
- no exercise of the option granted to the underwriters to purchase up to _____ additional ordinary shares to cover over-allotments, if any, in connection with this offering; and
- no exercise of warrants held by warrant holders allowing for the purchase of an aggregate of 136,773 Class A shares, which will be converted into a right to purchase an aggregate of _____ ordinary shares in connection with the Share Conversion.

SUMMARY FINANCIAL INFORMATION

The summary statement of profit or loss and statement of financial position for the years ended and as of December 31, 2013 and 2012 of Forward Pharma A/S are derived from the audited consolidated financial statements as of December 31, 2013 and 2012 and January 1, 2012 and for each of the two years in the period ended December 31, 2013 (the Consolidated Financial Statements) included in this Prospectus. We have prepared our consolidated financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or the IASB. The historical results set forth below are not necessarily indicative of the results expected in future periods.

This summary financial information should be read in conjunction with “Presentation of Financial and Other Information,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements, including the notes thereto, included in this Prospectus.

Consolidated statement of profit or loss data

(USD in thousands, except share and per share data)	Year ended December 31,	
	2013	2012
Research and development costs	(8,018)	(4,445)
General and administrative costs	(1,014)	(928)
Operating loss	(9,032)	(5,373)
Fair value adjustment to net settlement obligations to shareholder warrants	(6,676)	(17,071)
Other finance costs	(84)	(35)
Net loss before tax	(15,792)	(22,479)
Income tax	96	0
Net losses for the year	(15,696)	(22,479)
Net loss per share		
Basic and diluted	(9.53)	(14.25)
Weighted-average shares outstanding used to calculate net loss per share		
Basic	1,598,530	1,577,261
Diluted	1,598,530	1,577,261

Consolidated statement of financial position data

(USD in thousands)	As of December 31,	
	2013	2012
Cash and cash equivalents	2,955	828
Adjusted working capital (1)	2,317	213
Total assets	3,599	970
Long-term debt, including current portion	2,613	2,100
Accumulated (deficit)	(51,913)	(36,796)
Total shareholders’ equity	(26,415)	(20,250)

- (1) We define adjusted working capital as current assets minus trade and other payables. We use adjusted working capital to, among other things, evaluate our short-term liquidity requirements. We find adjusted working capital a useful metric in evaluating our short-term liquidity requirements because it eliminates the impact of shareholder warrants.

Adjusted working capital is not a U.S. GAAP or IFRS measure, and our definition may vary from that used by others in our industry. Accordingly, our use of adjusted working capital has limitations as an analytical tool and you should not consider it in isolation or as a substitute for analysis of our financial position as reported under IFRS.

RISK FACTORS

You should carefully consider the risks and uncertainties described below and the other information in this Prospectus before making an investment in our ordinary shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our ordinary shares could decline and you could lose all or part of your investment. This Prospectus also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

Risks Related to Our Business and Industry

We are a clinical-stage company with no approved products and no historical product revenues, which makes it difficult to assess our future prospects and financial results.

We are a biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing our formulation technology and undertaking pre-clinical studies and clinical trials of our proposed drug candidate FP187. As an early stage company, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biopharmaceutical area. Consequently, the ability to accurately assess our future operating results or business prospects is more limited than if we had a longer operating history or approved products on the market. Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with an early-stage drug development company, many of which are outside our control, and the occurrence of any setbacks could adversely affect our business and prospects.

We depend entirely on the success of our only clinical candidate, FP187. We cannot give any assurance that this clinical candidate will successfully complete clinical trials or receive regulatory approval, which is necessary before it can be commercialized.

We have invested almost all of our efforts and financial resources in the development of FP187. As a result, our business and future success is almost entirely dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize FP187, which has completed Phase 1 testing in healthy volunteers for release characteristics and tolerability, as well as a Phase 2 trial in moderate to severe psoriasis patients, and is being prepared for Phase 3 trials for RRMS and psoriasis. FP187 will require additional pre-clinical and clinical development, management of clinical and manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply, building of or partnering with a commercial organization, and substantial investment and significant marketing efforts before any revenues can be generated from product sales. We are not permitted to market or promote FP187 before we receive regulatory approval from the FDA, the EC or other foreign regulatory authorities, and we may never receive such regulatory approval for FP187. We cannot assure you that our clinical trials for FP187 will be completed in a timely manner, or at all, or that we will be able to obtain marketing approvals or labeling from the FDA, the EC or other foreign regulatory authorities necessary or desirable for the successful commercialization of FP187. If FP187 or any future product candidate is not approved and commercialized, we will not be able to generate any product revenues, which would materially affect our business, financial condition and result of operations. Moreover, any delay or setback in the development of any product candidate could adversely affect our business and prospects.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel, including a Chief Financial Officer.

Our success depends upon the continued contributions of our management, scientific and technical personnel, many of whom have substantial experience with or been instrumental for us and our development of FP187. These individuals currently include the members of our board of directors consisting of our Chairman, Florian Schönharting, as well as J. Kevin Buchi and Torsten Goesch, and our Chief Executive Officer and Chief Operating Officer, Peder Møller Andersen. Our senior scientific advisors include Dr. Kristian Reich, Dr. Ulrich Mrowietz, Dr. Fred D. Lublin, Dr. Per Soelberg Soerensen and Dr. Jerry Wolinsky.

The loss of managers and senior scientific advisors could materially delay our research and development activities and could have a material adverse effect on our business. In addition, the competition for qualified personnel in the biopharmaceutical field is intense, and our future success may depend upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees and consultants. We do not currently have a full-time Chief Financial Officer, or CFO, although we are in the process of recruiting someone to fill the position. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If we are unable to recruit a qualified CFO, or if in the future, our recruitment and retention efforts are unsuccessful, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

We expect to expand our drug development, regulatory and business development capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and consultants and the scope of our operations, particularly in the areas of drug development, regulatory affairs and business development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations, and have a materially adverse effect on our business.

Risks Related to Intellectual Property

We rely on patents and other intellectual property rights to protect our rights with respect to the development and commercialization of FP187 and other product candidates, the attainment, defense and maintenance of which may be challenging and costly. Failure to obtain, defend or maintain these rights adequately could materially adversely impact our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for FP187, as well as on the defense and exploitation of such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely impact our competitive advantage and impair our business.

Our patent portfolio consists primarily of two basic patent families, our “Core Composition Patent” family and our “Erosion Matrix Patent” family, along with three other patent families. We do not have any issued patents in the U.S. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. We have two granted patents in Europe: EP2316430, which covers DMF formulations with certain *in vitro* dissolution profiles, and EP2379063, which covers erosion matrix formulations with a thin enteric coating. Our other patent families include pending applications in Europe and the U.S. and are directed to new dosing regimens of DMF.

Both of our European patents have been opposed by third parties before the European Patent Office, or EPO. Multiple parties, including Biogen, are opposing before the EPO our patents EP2316430 and EP2379063. The EPO may determine that one or more of our claims are invalid and/or may require us to narrow the scope of the claims to avoid a finding of invalidity.

Moreover, our other pending applications may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, and the EPO and/or any patents issuing thereon may become involved in opposition, derivation, reexamination, inter parties review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights. Such third-party pre-issuance submissions have recently been filed with the USPTO, questioning each of the two U.S. patent applications from our Core Composition Patent family that have been allowed. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, and allow third parties to commercialize our technology or products and compete directly with us, without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to exploit our intellectual property or develop or commercialize current or future product candidates.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S., the EU and elsewhere. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit the duration of the patent protection of our technology and products. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition, other companies may attempt to circumvent any regulatory data protection or market exclusivity that we obtain under applicable legislation, which may require us to allocate significant resources to preventing such circumvention. Such developments could enable other companies to circumvent our intellectual property rights and use our clinical trial data to obtain marketing authorizations in the EU and in other jurisdictions. Such developments may also require us to allocate significant resources to prevent other companies from circumventing or violating our intellectual property rights.

Our attempts to prevent third parties from circumventing our intellectual property and other rights may ultimately be unsuccessful. We may also fail to take the required actions or pay the necessary fees to maintain our patents.

Intellectual property rights of third parties could adversely affect our ability to commercialize FP187, such that we could be required to litigate or obtain licenses from third parties in order to develop or market FP187. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our commercial success depends upon our ability and the ability of our potential collaborators to develop, manufacture, market and sell FP187 or other product candidates without infringing valid intellectual property rights of third parties. If a third-party intellectual property right exists that covers the composition of FP187 or the uses and dosages that the regulatory authorities approve for FP187, we may not be in a position to commercialize FP187 unless we successfully pursue litigation or administrative proceedings to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, which may not be available on commercially reasonable terms, if at all.

It is possible that we are unaware of all patents or applications relevant to the manufacture, use or commercialization of FP187. For example, we have not conducted a recent freedom to operate search in connection with FP187 and its use to treat MS. Any freedom to operate search previously conducted may not have uncovered all relevant patents and patent applications, and there may be pending or future patent applications that, if issued, would block us from commercializing FP187. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States (filed November 29, 2000 or later) and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering FP187 or its use to treat MS could have been filed by others without our knowledge. In addition, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover FP187 or the use of FP187. As a result, we do not know whether the manufacture, use, or commercialization of FP187 or any of our other product candidates will infringe any third-party patents with valid claims that have been or will in the future be issued.

Third-party intellectual property right holders, including our competitors, may actively bring infringement claims against us. We may not be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims or otherwise resolve such claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from, or experience substantial delays in, marketing our product candidates.

If we fail to settle or otherwise resolve any such dispute, in addition to being forced to pay damages, we or our potential collaborators may be prohibited from commercializing FP187 or other product candidates we may develop that are held to be infringing, for the duration of the patent term. We might, if possible, also be forced to redesign our formulations so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Biogen may initiate legal proceedings alleging that we are infringing its intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Biogen has several issued patents and is also prosecuting a number of additional patent applications that could adversely impact our commercial efforts if FP187 were ultimately found to infringe any valid claim by Biogen, in particular if Biogen obtains patent term extensions for certain key patents in the U.S. and/or Supplemental Protection Certificates (which also extend the effective life of patents for drugs) in the EU.

We are aware of the six patents Biogen has listed in the FDA's "Orange Book" (See "Business – Government Regulation – United States – Hatch-Waxman Act and Orange Book Listing.") in connection with Tecfidera®, U.S. Patent Nos. 6,509,376, 7,320,999, 7,619,001, 7,803,840, 8,399,514, and 8,524,773. Our planned regulatory path does not require that we make patent certifications to the FDA in connection with Biogen's Orange Book-listed patents, and at least three of the patents will expire before we anticipate receiving marketing approval for FP187.

We are also aware of U.S. Patent No. 8,399,514 and its European counterpart, EP2137537 B1. As discussed with respect to our "Core Composition" patent family, we have opposed EP2137537 B1 and are seeking to trigger an interference between one of our U.S. applications and Biogen's U.S. Patent No. 8,399,514.

In the U.S., Biogen's pending patent applications include U.S. Application no. 13/266,997, U.S. Application no. 14/119,373, U.S. Application no. 14/124,562, U.S. Application no. 13/760,916, and U.S. Application no. 13/827,228. In Europe, Biogen's pending patent applications include EP10770066 and EP1278291.

We believe that if such Biogen patents or patent applications (if issued as currently pending) are asserted against us, we would have defenses against such claims, including defenses of non-infringement and/or invalidity. The outcome of such potential proceedings would be unpredictable and if such patents were asserted against us and held to be valid, enforceable and infringed by the commercialization of FP187, we could be prevented from continuing to commercialize our product candidates, unless we obtain a license to such patents, which may not be available on commercially reasonable terms or at all. If we market FP187 and are later found to infringe one or more of Biogen's patents, we could also be required to pay substantial damages.

We may become involved in lawsuits to protect and defend our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file claims, and any related litigation and/or prosecution of such claims can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid in whole or in part, unenforceable, or construe the patent's claims narrowly allowing the other party to commercialize competing products on the grounds that our patents do not cover such products.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. The effects of patent litigation or other proceedings could therefore have a material adverse effect on our ability to compete in the marketplace.

We enjoy only limited geographical protection with respect to certain of our patents and may face difficulties in certain jurisdictions, which may diminish the value of our intellectual property rights in those jurisdictions.

Our two earliest and broadest patent filings, PCT/DK2005/000648 and PCT/EP2010/050172, have limited geographic reach beyond the U.S. and Europe. PCT/DK2005/000648 has multiple pending U.S. counterparts, a granted European patent, a pending European patent application and a pending Japanese counterpart. PCT/EP2010/050172 has a U.S. counterpart pending, a European patent granted, a European application pending, has Australian, Canadian, Japanese, Eurasian, Indian, Chinese, Korean and Russian counterparts pending and a granted patent in the Ukraine. We may decide to abandon national and regional patent applications outside Europe and the U.S. before they are granted, if at all. Our later filed patent applications, disclosing new dosing regimens for FP187, have not yet been filed outside of the U.S. and the EU. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product. For example, in some jurisdictions, it is not possible to obtain patents on new dosing regimens.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the U.S. and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our collaboration partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

Third parties may claim rights in our intellectual property.

None of the named inventors on our intellectual property were our employees at the time of the filing of the Core Compositions patent family, which we acquired from Aditech. Two of the named inventors of the Core Compositions patent family were consultants of Aditech and, while obligated under their consulting agreements to assign their rights in the Core Compositions patent family to Aditech, were employed by other institutions at the time they made their inventions. While such institutions have not made any ownership claims to the inventions disclosed in the Core Compositions patent family, there can be no assurance they will not do so in the future.

Later-filed patent families were filed by us, but some of the named inventors were acting only in a consultant capacity to us. Some of these consultants, while obligated under their consulting agreements to assign their rights in such patent families to us, were employed by other institutions prior to or at the time they made their inventions. While such institutions have not made any ownership claims to the inventions disclosed in the later-filed patent families, there can be no assurance they will not do so in the future.

Named inventors on our patent applications, whether filed by us or acquired from Aditech, could also challenge whether their property rights were properly assigned, if at all. Further, other individuals (including persons not known to us) could make claims or assertions that they are inventors of our intellectual property.

Under mandatory Danish law, an employee having made a patentable invention (and products that may be subject to registration as an industrial designer right) through his service with an employer has the rights to such invention, provided however, that the rights to the patentable invention upon the employer's request shall be transferred to the employer against the employer's payment to the employee of a "reasonable compensation." The fee shall be fixed considering the value of the invention and its consequences for the employer, the employee's terms of employment and the impact that the employee's service has had for the invention. In the event that the value of the invention does not exceed what the employee, taking his working conditions as a whole into account, reasonably could be expected to achieve, the employee is not entitled to any fee. The compensation payable by the employer is not subject to any maximum amount and may be paid either as a lump sum or as a continuing royalty payment based on e.g. per produced item based on the invention. An employee's claim for compensation may become time-barred or forfeited due to the employee's passive behavior. The general time-barring regulation under Danish law is five years with respect to claims based on employment matters.

Some of the named inventors on patent applications relating to dosing regimens of DMF are employees of our German subsidiary Forward Pharma GmbH and thus are subject to German employment law. German employment law governs the transfer/assignment of any intellectual property rights generated by such employees. In particular, any inventions eligible for patent protection made by such employees are subject to the provisions of the German Act on Employees' Inventions (Gesetz über Arbeitnehmererfindungen), which regulates the ownership of, and compensation for, inventions made by employees. The law provides for a formal procedure for the transfer of employee's rights to a patentable invention upon employer's request within a certain period of time after notification by employee.

We believe that inventive contributions made by employees of Forward Pharma GmbH were made after the amended version of the German Act on Employees' Inventions came into force on October 1, 2009 and thus the amended version of the law exclusively applies to such inventions. The amendments to the law facilitate the transfer of rights in employees' inventions to the employer by replacing the former opt-in approach by an opt-out approach.

Following the transfer of rights, an employee is entitled to a claim for "reasonable compensation" to be calculated on an individual basis (e.g., revenue achieved through exploitation of the patent). In addition, the German Act on Employees' Invention provides for certain obligations on the employer including the obligation to apply for patent protection in Germany, the obligation to release the invention for application in those countries where the employer does not want to apply for a patent and the obligation to offer to the employer granted patents or pending patent applications if the employer intends to abandon rights in any country.

We face the risk that disputes can occur between us and employees or ex-employees of Forward Pharma GmbH pertaining to alleged non-adherence to the provisions of this act. Such disputes may be costly to defend and take up our management's time and efforts whether we prevail or fail in such dispute. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- Others may be able to make DMF-based products that are similar to FP187 but that are not covered by the claims of the patents that we own.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- We or any of our collaboration partners might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license.
- We or any of our collaboration partners might not have been the first to file patent applications covering certain of the patents or patent applications that we or they own or have obtained a license, or will own or will have obtained a license.
- It is possible that our pending patent applications will not lead to issued patents.

- Issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- The patents of third parties may have an adverse effect on our business.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products or product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and exploiting patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and exploiting biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the America Invents Act, or AIA, has been recently enacted in the United States, resulting in significant changes to the U.S. patent system. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to exploit our existing patents and patents that we might obtain in the future. Similarly, the complexity and uncertainty of European patent laws has also increased in recent years. In addition, the EP patent system is relatively stringent in the type of amendments that are allowed during prosecution. Changes in patent law or patent jurisprudence could limit our ability to obtain new patents in the future that may be important for our business.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third-party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

Our information technology systems could face serious disruptions that could adversely affect our business.

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions in our collaborations with our partners and delays in our research and development work.

Risks Related to the Development, Clinical Testing, Regulatory Approval and Commercialization of FP187.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of FP187 are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize FP187 on a timely basis or at all.

To obtain the requisite regulatory approvals to market and sell FP187, we must demonstrate through extensive pre-clinical and clinical trials that it is safe and effective in humans for its intended use. The process for obtaining governmental approval to market FP187 is rigorous, time-consuming and costly. It is impossible to predict the extent to which this process may be affected by legislative and regulatory developments. Due to these and other factors, FP187 or future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of FP187.

Clinical trials must be conducted in accordance with FDA, EMA and other applicable regulatory authorities' legal requirements, regulations or guidelines, including good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors. Clinical trials are further subject to oversight by these governmental agencies and Institutional Review Boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of FP187 produced under current good manufacturing practices, or cGMP, and other requirements. Our clinical trials are conducted at multiple sites, including some sites in countries outside the U.S. and the EU, which may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-U.S. and non-EU clinical research organizations, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the European regulatory authorities, and with different standards of diagnosis, screening and medical care.

To date, we have not completed all clinical trials required for the approval of FP187, which is currently being prepared for Phase 3 testing. The commencement and completion of clinical trials for FP187 may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- negative or inconclusive results, which may require us to conduct additional pre-clinical or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site and changes in regulatory requirements, policies and guidelines;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- delays or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our third-party research and manufacturing contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;

- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of FP187 falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of FP187 to complete clinical trials; and
- exceeding budgeted costs due to difficulty in predicting accurately costs associated with clinical trials.

Positive or timely results from pre-clinical studies and early stage clinical trials do not ensure positive or timely results in late stage clinical trials or product approval by the FDA, the EMA or other regulatory authorities.

Products that show positive pre-clinical or early clinical results may not show sufficient safety or efficacy to obtain regulatory approvals and therefore fail in later stage clinical trials. The FDA, the EMA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for FP187. Even if we believe the data collected from clinical trials of FP187 are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Monitoring Committee, or DMC, for such trial or by the FDA, the EMA or other regulatory authorities. We or such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, the EMA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using the drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of FP187, the commercial prospects of FP187 will be harmed, and our ability to generate product revenues from this product will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow the FP187 development and approval process and jeopardize our ability to commence product sales and generate revenues.

Any of these occurrences could materially adversely affect our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of FP187. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize FP187 and impair our ability to commercialize FP187 and may harm our business and results of operations.

The FDA and/or the EMA/ EC may determine that our proposed single Phase 3 trial for the use of FP187 for the treatment of RRMS, including any SAD data generated through the date of our NDA submission, is insufficient for approval of FP187, which would delay or could prevent the approval of FP187 and adversely affect our prospects.

To advance FP187 for use as a drug to treat RRMS in the U.S., in August 2013 we held a pre-Investigational New Drug, or IND, Application meeting with the FDA, prior to which we submitted a briefing book including a proposal for a large, single Phase 3 trial. Approval by the FDA of a New Drug Application, or NDA, is dependent on a number of factors. A final decision as to whether the program we shared with the FDA at a high level in advance of our pre-IND meeting will be sufficient for approval (including the sufficiency of our proposed single Phase 3 trial and whether a favorable change in SAD will need to be demonstrated by us at the time of our NDA submission) can only be made by the FDA once it has reviewed our full NDA, including the data from our Phase 3 trial. In addition, since we intend to rely on a single Phase 3 trial to demonstrate the effectiveness of FP187, the usual demonstration of the statistical significance of the superiority of FP187 to the active comparator drug in the primary efficacy endpoint ($p=0.05$) is unlikely to be sufficient to obtain approval of FP-187, and so we are likely to be required to demonstrate robust statistical significance of the superiority of FP187 to the active comparator drug.

There can, however, be no assurances that the FDA will ultimately accept the data from our single Phase 3 trial (or what SAD data we have generated at the time of submission or at a later date) as sufficient for approval when we file our NDA or at all, or that we will be able to timely file such an NDA. Similarly, in the EU, we may experience a delay in submitting our market authorization application to the EMA and can have no assurances that the EC ultimately will approve FP187 as a drug for the treatment of RRMS.

If serious adverse, undesirable or unacceptable side effects are identified during the development or commercialization of FP187, we or our collaboration partners may need to abandon or limit development or commercialization of FP187.

If FP187 or any other product candidate we develop is associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon such candidate's development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in early-stage or clinical testing have later been found to cause side effects that prevented further development of the compound.

Undesirable side effects caused by FP187 or another product candidate we develop could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EC or other comparable foreign authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, EMA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences could materially adversely affect our business, financial condition and prospects.

It is documented in the Tecfidera® labeling and through experience using Fumaderm® that the use of products containing DMF, the sole API in FP187, may cause a decrease in lymphocytes (white blood cells) in humans, thereby possibly increasing the potential for infection. To date, we are not aware of instances in which this side effect has prevented the FDA or the EC from approving RRMS drugs such as Tecfidera®, although it is expected that each of the FDA and the EMA will require us to monitor the incidence of this condition, known as lymphopenia and will evaluate whether FP187 increases the potential for infections during the review of our NDA in the U.S. and market authorization application in the EU.

If FP187 or another product candidate we develop receives marketing approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the labeling;
- we or our collaboration partners may be required to create a medication guide or risk evaluation and mitigation strategies, or REMS, addressing the risks of such side effect;
- we or our collaboration partners could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of FP187 or any other product candidate, if approved, and could materially adversely affect our business, financial condition and prospects.

Positive results in previous clinical trials of FP187 may not be replicated in future clinical trials of FP187, which could result in development delays or a failure to obtain marketing approval.

Positive results in previous clinical trials of FP187 may not be predictive of similar results in future clinical trials. In addition, interim results during a clinical trial do not necessarily predict final results. A number of companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials even after achieving promising results in early-stage development. Accordingly, the results from the completed pre-clinical studies and clinical trials for FP187 may not be predictive of the results we may obtain in later stage trials. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain FDA or EMA/EC approval for their products.

We depend on enrollment of patients in our clinical trials for FP187. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the nature of the trial protocol, competing clinical trials and the availability of new drugs approved for the indication the clinical trial is investigating.

With respect to our clinical development of FP187 in RRMS, our proposed Phase 3 trial is particularly ambitious, requiring the recruitment of up to 2,000 patients worldwide. We have no experience in managing a clinical trial of this scope, in centers throughout the world, and we will need to significantly increase our clinical development resources in order to successfully manage and oversee this process.

Enrollment of a sufficient number of patients in the Phase 3 trial for RRMS, the size of which is, to our knowledge, unprecedented for drugs intended for the treatment of RRMS, will depend on our ability to convince physicians and patients at the trial sites of the clinical meaningfulness of our study, and the recent availability of oral therapies such as Gilenya® (fingolimod), Aubagio® (teriflunomide) and Tecfidera® (another DMF formulation) may cause patients to be less willing to participate in our clinical trial for an oral therapy in regions in which one of these alternative oral therapies has been approved. Since RRMS is a competitive market in certain regions, such as the U.S. and the EU, with a number of drug candidates in development, patients may have other choices with respect to potential clinical trial participation and we may have difficulty reaching our enrollment targets. In addition, the relatively limited number of RRMS patients worldwide (estimated at 2 – 2.5 million) may make enrollment more challenging.

Instability in Russia and the CIS could adversely affect our planned European Phase 3 clinical trial for FP187 for the treatment of psoriasis.

We are continuing advanced preparatory work for an active comparator and placebo controlled confirmative non-inferiority Phase 3 trial of FP187 for the treatment of psoriasis in Europe, as well as an additional placebo controlled Phase 3 trial of FP187 for the treatment of psoriasis in the United States. Our planned Phase 3 trial in Europe would consist of approximately 60 clinical sites, of which 23 are in Russia and the Ukraine. The implementation of sanctions in Russia and/or the Ukraine, or the exacerbation of or continued political instability in the region could adversely impact our ability to perform studies in the region, or could increase the costs to us and our clinical research organizations, or CROs, in performing such studies. As a result, our ability to proceed or continue with sites in these countries could be adversely impacted.

We may become exposed to costly and damaging liability claims, either when testing FP187 or any other product candidates we develop in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently we have no products that have been approved for commercial sale; however, the current and future use of FP187 or other product candidates by us and our collaboration partners in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our collaboration partners or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for FP187 or any prospects for commercialization of FP187.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If FP187 were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use FP187.

Although we maintain limited product liability insurance for FP187, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for FP187. However, we may be unable to obtain any insurance covering the sale of FP187, once commercialized, or may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Our product candidate FP187 is subject to extensive regulation, compliance with which is costly and time consuming, may cause unanticipated delays, or prevent the receipt of the required approvals to commercialize our product candidate.

We and our collaboration partners are not permitted to market our product candidate FP187 until we receive regulatory approval from regulatory authorities. The process of obtaining regulatory approval is expensive, often takes many years, and can vary substantially based upon the type, complexity, and novelty of the products involved, as well as the target indications. Approval policies or regulations may change and regulatory authorities have substantial discretion in the drug approval process, including the ability to delay, limit, or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

The FDA, the EMA or other comparable foreign regulatory authorities can delay, limit, or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or implementation of our clinical trials or the adequacy of our pre-clinical studies;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other regulatory authorities that a product candidate is safe and effective for any indication;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from the United States;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- such authorities may find deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

In addition, competitors could attempt to use the regulatory process to attempt to delay or prevent approval of FP187. For example, a competitor could file a citizen petition with the FDA seeking a ruling from the FDA that the use of a single Phase 3 trial as a basis for approving FP187 is not appropriate. We believe that, if our proposed Phase 3 trial for FP187 is successful and the results meet our expectations, the FDA will have a proper basis for approving our NDA for FP187. However, the filing of a citizen petition could delay any approval of FP187 by the FDA, which would adversely affect our prospects.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

Even if FP187 obtains regulatory approval, it will be subject to continual regulatory review.

If marketing authorization is obtained for FP187, it will remain subject to continual review and therefore authorization could be subsequently withdrawn or restricted. We and our collaboration partners will be subject to ongoing obligations and oversight by regulatory authorities, including adverse event reporting requirements, marketing restrictions and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize FP187. We and our collaboration partners will also be subject to regulatory requirements covering the manufacturing of FP187, including maintaining compliance with cGMP, and our contract manufacturers will be subject to periodic inspections by regulatory authorities.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our collaboration partners fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning and/or untitled letters to us, imposing fines on us, imposing restrictions on FP187 or its manufacture, requiring us to recall or remove the product from the market, entering an injunction against us, requiring us to enter into a consent decree, and pursuing criminal prosecution against us. The regulators could also suspend or withdraw our marketing authorizations or require us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

The FDA, the EMA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of uses not consistent with approved product labeling. If we are found to have improperly promoted such uses, we may become subject to significant liability.

The FDA, the EMA and other regulatory authorities strictly regulate the promotional claims that may be made about prescription products, such as FP187, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA, the EMA or such other regulatory agencies as reflected in the product's approved labeling. For example, the FDA requires substantial evidence, which generally consists of two adequate and well controlled head-to-head clinical trials, for a company to make a claim that its product is superior to another product. Unless we perform clinical trials comparing FP187 to Tecfidera®, we will not be able promote FP187 by making comparative claims to Tecfidera®. If we are found to have made such claims we may become subject to significant liability. In the U.S., the federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in improper promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Due to our limited resources and access to capital, we must decide to prioritize development of FP187 for certain indications and at certain doses; these decisions may prove to have been wrong and may materially adversely affect our business, financial condition, results of operations and prospects.

Because we have limited resources and access to capital to fund our operations, we must decide which dosages and indications to pursue for the clinical development of FP187 and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward dosages or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the market potential of FP187 or misread trends in the biopharmaceutical industry, our business, financial condition, results of operations and prospects could be materially adversely affected.

Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may disrupt or delay our production and development efforts and materially adversely affect our business, financial condition and results of operations.

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize FP187 and may affect the prices we may set.

In the U.S., the EU and some other foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could prevent or delay marketing approval of FP187, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

In the U.S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, or ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the ACA revised the definition of “average manufacturer price” for reporting purposes, which could increase the amount of Medicaid drug rebates to states. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with health care practitioners. We will not know the full effects of the ACA until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the ACA, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

Both in the U.S. and in the EU, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are not sure whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of FP187, if any, may be.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations include the following:

- the U.S. healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under U.S. healthcare programs such as Medicare and Medicaid;
- the U.S. False Claims Act imposes criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the U.S. Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the U.S. false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits items or services;
- the transparency requirements under the ACA require manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biopharmaceutical industry is highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in the U.S., the EU and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with FP187.

We believe that our key competitor in the commercialization of DMF for RRMS is Biogen, which has developed Tecfidera®, an oral treatment with RRMS. Tecfidera® has been approved in the U.S., Canada, Australia and the EU. The fact that Tecfidera® has been commercialized and is being marketed in the U.S. may render our development and discovery efforts in the area of DMF for the treatment of RRMS uncompetitive. Other companies are also developing alternative therapeutic approaches to the treatment of RRMS. These alternative therapeutic approaches may be used as complementary to the use of FP187 for the treatment of RRMS, but they could also be competitive.

The highly competitive nature of and rapid technological changes in the pharmaceutical and biotechnological industries could render FP187 or our technology obsolete or non-competitive. Our competitors may, among other things:

- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain quicker regulatory approval;
- establish superior proprietary positions;
- have access to more manufacturing capacity;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected.

The successful commercialization of FP187 and any other products we develop will depend, in part, on the extent to which governmental authorities, health insurers and other third-party payors establish adequate reimbursement levels and pricing policies.

The successful commercialization of FP187 and any other products we develop will depend, in part, on the extent to which third-party coverage and reimbursement for our product will be available from government and health administration authorities, private health insurers and other third-party payors.

These bodies may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Obtaining and maintaining reimbursement status is time-consuming and costly. Significant uncertainty exists as to the reimbursement status of newly approved medical products. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely. In addition, many governments and health insurers are increasingly attempting to manage healthcare costs by limiting both coverage and the level of reimbursement of new products. As a result, they may not cover or provide adequate payment for our future products.

These concerns are particularly present for drugs like FP187 that use an API that is already available in other, approved drugs. Public and private payors may only be willing to provide coverage for FP187 if we can demonstrate a significant clinical advantage, or offer the drug at a price resulting in a treatment cost lower than other available drugs. Public and private payors may not be willing to grant reimbursement prices in line with our expectations if they do not share our views concerning the advantages of our proprietary formulation technology, in particular if they do not give as much weight as we do to, for example, what we expect will be reductions in flushing as a side effect.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of FP187 and the future revenues we may expect to receive from it. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

FP187 and any other products we develop may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.

Even if the FDA, the EMA or any other regulatory authority approves the marketing of any products that we develop on our own or with a collaboration partner, physicians, healthcare providers, patients or the medical community may not accept or use them. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of FP187 will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other insurers, both public and private; and
- other potential advantages over alternative treatment methods.

If FP187 or any other product we develop fails to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may not prove to be large enough to allow us to generate significant revenues.

We have never commercialized a product candidate, and we currently have no marketing and sales organization. To the extent our product candidate FP187 is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell FP187 or generate product revenue.

We have never commercialized a product candidate, and we currently do not have a marketing or sales organization for the marketing, sales and distribution of FP187 and do not intend to create one. In order to commercialize any of our products that receive marketing approval, we would have to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development of FP187, if we elect to build a targeted specialty sales force, such an effort would be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to FP187, we may choose to partner with third parties that have their own sales forces and established distribution systems, in lieu of or to augment any sales force and distribution systems we may create. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able to successfully commercialize FP187 if it receives regulatory approval. If we are not successful in commercializing FP187, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

Risks Related to our Financial Position and Capital Needs

We have a history of operating losses, and we may not achieve or sustain profitability. We anticipate that we will continue to incur losses for the foreseeable future. If we fail to obtain additional funding to conduct our planned research and development effort, we could be forced to delay, reduce or eliminate our product development programs or commercial development efforts.

We incurred net losses of \$15.7 million and \$22.5 million for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we had an accumulated deficit of \$51.9 million. Our losses have resulted principally from expenses incurred in research and development of FP187, from general and administrative expenses that we have incurred while building our business infrastructure, and from fair value adjustments to net settlement obligations to shareholder warrants. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of FP187. In our fiscal year ending December 31, 2014, we expect to incur approximately \$32.0 million of costs associated with research and development.

To date, we have financed our operations through private placements of equity securities, grants from governmental bodies, and debt financing arrangements. We have never generated any revenues from product sales. Based on our current plans, we do not expect to generate significant royalty or product revenues unless and until we obtain marketing approval for, and commercialize, FP187. We believe that the net proceeds of this offering, together with the bridge financing we expect to enter into prior to consummation of this offering and our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We may have to seek additional funding beyond the expected net proceeds from this offering. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. In addition, we may not be able to obtain further funding from governmental bodies.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a consistent basis or at all. Our failure to sustain profitability could depress the market price of our ordinary shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations. A decline in the market price of our ordinary shares also could cause you to lose all or a part of your investment.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements included in this Prospectus.

Our audited consolidated financial statements were prepared assuming that we will continue as a going concern. However, the report of our independent registered public accounting firm included elsewhere in this Prospectus contains an explanatory paragraph on our consolidated financial statements stating there is substantial doubt about our ability to continue as a going concern, meaning that we may not be able to continue in operation for the foreseeable future or be able to realize assets and discharge liabilities in the ordinary course of operations. Such an opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may also make it more difficult to raise additional funds or operate our business due to concerns about our ability to meet our contractual obligations.

Based on current operating plans, our most recent forecasts show that we have resources to fund our operations until April 2014, but will require further funds to finance our activities from April until December 2014. We currently expect to enter into a bridge financing prior to consummation of this offering. Should neither the bridge financing nor this offering be consummated as expected we will need to consider alternative arrangements and such arrangements could have a potentially significant negative impact on our ability to continue our operations.

Raising additional capital may cause dilution to our shareholders, including purchasers of ordinary shares in this offering, restrict our operations or require us to relinquish rights to our technologies or products.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of the net proceeds of this offering, together with our existing cash and cash equivalents. We also anticipate entering into a bridge financing which we anticipate will be convertible into or exchangeable for certain of our equity securities. In the event we need to seek additional funds, we may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our ordinary shares. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our ordinary shares to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or products or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market FP187 or other product candidates that we would otherwise prefer to develop and market ourselves.

Exchange rate fluctuations or abandonment of the Euro currency may materially affect our results of operations and financial condition.

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the DKK and the U.S. dollar, may adversely affect us. Although we are based in Denmark, we source research and development, manufacturing, consulting and other services from several countries. Further, potential future revenue may be derived from abroad, particularly from the United States. As a result, our business and our ordinary share price may be affected by fluctuations in foreign exchange rates between the Danish Kroner and the U.S. dollar or such other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place and do not currently have plans to implement any hedging arrangements.

In addition, the possible abandonment of the Euro by one or more members of the EU could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the Euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU member states from the EU or the abandonment of the Euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

Related party transactions may be challenged by tax authorities.

Many of the jurisdictions in which we conduct or will conduct business, and in particular Denmark and Germany, have detailed transfer pricing rules which require that all transactions with related parties be priced using arm's length pricing principles. Contemporaneous documentation must exist to support this pricing. The taxation authorities in these jurisdictions could challenge our arm's length related party transfer pricing policies. International transfer pricing is an area of taxation that depends heavily on the underlying facts and circumstances and generally involves a significant degree of judgment. Although we believe that our related-party transactions satisfy the substantive requirements of these transfer pricing rules, if any of these taxation authorities are successful in challenging our transfer pricing policies, our income tax expense may be adversely affected and we could also be subjected to interest and penalty charges. Any increase in our income tax expense and related interest and penalties could have a significant impact on our future earnings and future cash flows.

Risks Related to Our Dependence on Third Parties

If we fail to enter into strategic relationships or collaborations our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of FP187 or any other product candidates we develop will require substantial additional cash to fund expenses. Therefore, in addition to financing the developments of FP187 or any other product candidates we develop through additional equity financings or through debt financings, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of such products or product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular product, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring FP187 to market and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to the product development program;
- the collaboration partner may experience financial difficulties and thus not commit sufficient financial resources to the product development program;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaboration partner could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaboration partner's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

We currently rely on third-party suppliers and other third parties for production of FP187 and our dependence on these third parties may impair the advancement of our research and development programs and the development of FP187.

We currently rely on and expect to continue to rely on third parties for the supply of raw materials and manufacture of drug supplies necessary. We have a single contractual relationship with a manufacturer (a so-called contract manufacturing organization, or CMO) to purchase, develop and manufacture our DMF. We also have a single contractual relationship with another CMO for the formulation, development, manufacture, analysis, packaging and supply of our DMF tablets. For the foreseeable future, we expect to continue to rely on only these two third parties.

Reliance on just one CMO for each of the manufacturing of DMF and our delivery formulation may expose us to more risk than if we were to manufacture FP187 or other products ourselves, or if we were to have relationships with multiple or back-up third parties. Delays in production by either of these third parties could delay our clinical trials or have an adverse impact on any commercial activities. In addition, the fact that we are dependent on these two third parties for the manufacture of DMF and formulation of FP187, respectively, means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. Although we oversee these activities to ensure compliance with our quality standards, budgets and timelines, we have had and will continue to have less control over the manufacturing of DMF than potentially would be the case if we were to manufacture FP187 ourselves, or have alternative CMOs to turn to in instances where batches of our FP187 did not meet required standards. Further, the CMOs we deal with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, which would adversely affect the manufacturing of DMF and the production of our FP187 tablets.

We are obliged to work with CMOs and third-party suppliers that comply with EMA, FDA or other regulatory authorities' laws and regulations, including cGMPs, on an ongoing basis. Although we are ultimately responsible for ensuring compliance with these regulatory requirements, we do not have day-to-day control over a CMO or other third-party manufacturer's compliance with these laws, regulations and applicable cGMPs and other laws and regulations, such as those related to environmental health and safety matters. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of FP187 or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers, such as our CMOs, may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties, business priorities or other reasons, at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

The manufacture of DMF requires highly specialized safety procedures and equipment and is therefore carried out by a limited number of CMOs. Our Phase 3 trial for FP187 and commercialization of FP187, when and if initiated, will greatly increase our requirements for DMF. While we are currently searching for alternative and/or supplementary sources of production, there can be no assurance that we will be able to locate such alternatives or that we will be able to agree on the commercial terms of any supply agreements with such CMOs, which could impact negatively on our programs. The inability of our single third-party source of DMF to meet our requirements for DMF would have a material adverse impact on our business and prospects.

Problems with the quality of the work of third parties, such as CMOs, may lead us to seek to terminate our relationships and use alternative service providers. However, making this change may be costly and may delay the trials, and contractual restrictions may make such a change difficult or even impossible. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture the necessary DMF or tablets in an acceptable manner and at an acceptable cost and on a timely basis. The sale of products containing any defects or any delays in the supply of necessary services could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely affect our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, supplies may not be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

If we fail to retain accounting and financial staff with appropriate experience, our ability to maintain the financial controls required of a public company may adversely affect our business.

We currently rely on third-party accounting professionals to assist us with our financial accounting and compliance obligations. We are seeking financial professionals with appropriate experience to maintain our financial control and reporting obligations as a public company. If we are unable to identify and retain such qualified and experienced personnel, our business may be adversely impacted.

Risks Related to the Offering and Our Ordinary Shares

The price of our ordinary shares may be volatile and may fluctuate due to factors beyond our control.

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our ordinary shares may fluctuate significantly due to a variety of factors, including:

- developments concerning proprietary rights, including patents and litigation matters;
- positive or negative results of testing and clinical trials by us, strategic partners, or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of FP187 or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- public concern relating to the commercial value or safety of FP187;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors beyond our control.

In addition, the stock market in general has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may materially affect the market price of companies' shares, including ours, regardless of actual operating performance.

There was no public market for our ordinary shares prior to this offering, and an active market in the shares may not develop in which investors can resell our ordinary shares.

Prior to this offering there was no public market for our Class A shares or our Class B shares, each of which will be converted into ordinary shares prior to consummation of this offering. We cannot predict the extent to which an active market for our ordinary shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our ordinary shares. The initial public offering price of our ordinary shares in this offering was agreed between us and the underwriters based on a number of factors, including market conditions in effect at the time of this offering, which may not be indicative of the price at which our shares will trade following completion of this offering. Investors may not be able to sell their shares at or above the initial public offering price.

Our principal shareholders currently own, in the aggregate, all of our outstanding Class A shares and Class B shares and will own approximately % of our ordinary shares upon the closing of this offering. They will therefore be able to exert significant control over matters submitted to our shareholders for approval.

After this offering, our shareholders who own more than 5% of our Class A shares and Class B shares before this offering will, in the aggregate, beneficially own approximately % of our ordinary shares (assuming no exercise of the underwriters' over-allotment option). These shareholders will be able to significantly influence or even unilaterally approve matters requiring approval by our shareholders, including the election of directors, certain decisions relating to our capital structure, amendments to our Articles of Association, and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of our other shareholders.

Our ordinary shares will be controlled by insiders, who could have significant influence over the outcome of corporate actions requiring board and shareholder approval.

Our Chairman, Florian Schönharting, beneficially owns shares comprising approximately 99% of our voting power, and after the offering, will beneficially own approximately % of our ordinary shares. With such concentrated control, Mr. Schönharting will have influence over the outcome of corporate actions requiring board and shareholder approval, including the election of directors or any other significant corporate transaction. As a result, investors who acquire ordinary shares in the offering may have no effective voice in the management of our company.

Future sales, or the perception of future sales, of a substantial number of our ordinary shares could adversely affect the price of the shares, and actual sales will dilute shareholders.

Future sales of a substantial number of our ordinary shares, or the perception that such sales will occur, could cause a decline in the market price of our ordinary shares. Following the completion of this offering, we will have ordinary shares outstanding (assuming no exercise of the underwriters' over-allotment option) based on ordinary shares being offered in the offering and ordinary shares which will be issued upon the conversion of our Class A shares and Class B shares into ordinary shares. This includes the shares in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Approximately of the shares outstanding immediately after this offering are expected to be held by existing shareholders. Assuming the purchase in this offering of of our ordinary shares by certain of our existing shareholders or their affiliates, the number of our ordinary shares beneficially owned by our existing shareholders will, in the aggregate, increase to of our ordinary shares. A significant portion of these shares will be subject to the lock-up agreements described in the "Underwriting" section of this Prospectus. If, after the end of such lock-up agreements, these shareholders sell substantial amounts of shares in the public market, or the market perceives that such sales may occur, the market price of our ordinary shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. We also intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. In addition, we intend to register all ordinary shares that we may issue under our equity compensation plans. Once we register these ordinary shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this Prospectus.

If you purchase ordinary shares in this offering, you will suffer immediate dilution of your investment.

The initial public offering price of our ordinary shares is substantially higher than the pro forma net tangible book value per Class A share and Class B share. Therefore, if you purchase ordinary shares in this offering, you will pay a price per share that substantially exceeds our pro forma net tangible book value per ordinary share after this offering. To the extent outstanding warrants are exercised, you will incur further dilution. Assuming a public offering price of the midpoint of the price range set forth on the cover page of this Prospectus of \$ per share, you will experience immediate dilution, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of ordinary shares in this offering will have contributed approximately \$ of the aggregate price paid by all purchasers of our ordinary shares but will own only approximately % of our ordinary shares outstanding after this offering. See "Dilution."

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that ultimately do not improve our results of operations or enhance the value of our ordinary shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our ordinary shares to decline and delay the development of FP187. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We do not expect to pay dividends in the foreseeable future.

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. Payment of future dividends to shareholders will effectively be at the discretion of our board of directors, subject to the approval of a majority of our voting shares after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future dividends may be made only if our shareholders' equity exceeds the sum of our paid-in and called-up share capital plus the reserves required to be maintained by Danish law or by our Articles of Association. Accordingly, investors cannot rely on dividend income from our ordinary shares and any returns on an investment in our ordinary shares will likely depend entirely upon any future appreciation in the price of our ordinary shares.

We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” will make our ordinary shares less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an “emerging growth company” we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of any June 30 date (the end of our second fiscal quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our fiscal year end). We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses.

As a foreign private issuer, we are not required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act and related rules and regulations. The determination of foreign private issuer status is made annually on the last business day of an issuer’s most recently completed second fiscal quarter. Accordingly, we will next make a determination with respect to our foreign private issuer status on June 30, 2014. There is a risk that we will lose our foreign private issuer status in the future.

We would lose our foreign private issuer status if, for example, more than 50% of our assets are located in the United States and we continue to fail to meet additional requirements necessary to maintain our foreign private issuer status. As of December 31, 2013, an immaterial amount of our assets were located in the United States, although this may change if we expand our operations in the United States. The regulatory and compliance costs to us under U.S. securities laws as a U.S. domestic issuer may be significantly greater than the costs we incur as a foreign private issuer. If we are not a foreign private issuer, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC rules to prepare our financial statements in accordance with U.S. GAAP and modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. Such conversion and modifications would involve additional costs. In addition, we may lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers, which could also increase our costs.

If we fail to establish and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Effective internal control over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

We will be required to disclose changes made in our internal control over financial reporting and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

If we are unable to successfully remediate material weaknesses in our internal control over financial reporting relating to inadequate financial statement preparation and review procedures, the accuracy and timing of our financial statements may be adversely affected. Further, these material weaknesses could impair our ability to comply with the accounting and reporting requirements within the International Financial Reporting Standards (IFRS) as issued by the IASB.

In connection with the audits of our financial statements, our independent registered public accounting firm identified a material weakness related to our financial statement closing process, primarily related to the lack of sufficient skilled personnel with IFRS and SEC reporting knowledge for the purposes of timely and reliable financial reporting. Specifically, our independent registered public accounting firm determined that we lacked sufficient accounting and finance resources to and did not design and operate procedures and controls over the preparation of our financial statements, including insufficient financial statement close process and procedures including account reconciliations, the resolution of complex accounting issues involving significant judgment and estimates and overall review of the financial statements.

Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We concurred with the findings of our independent registered public accounting firm. We are working to remediate the material weakness and are taking numerous steps and plan to take additional steps to remediate the underlying causes of the material weakness. We are currently in the process of recruiting a full-time Chief Financial Officer, and plan to further develop and implement formal policies, processes and documentation procedures relating to the financial reporting of the company. The actions that we are taking are subject to ongoing executive management review, and will also be subject to audit committee oversight. Although we plan to complete this remediation process as quickly as possible, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in remediating the material weakness. If we are unable to successfully remediate the material weakness, and if we are unable to produce accurate and timely financial statements, our share price may be adversely affected and we may be unable to comply with applicable stock exchange listing requirements.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our ordinary shares and our trading volume could decline.

The trading market for our ordinary shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our ordinary shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our ordinary shares or publish inaccurate or unfavorable research about our business, the price of our ordinary shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ordinary shares could decrease, which might cause the price of our ordinary shares and trading volume to decline.

We may be classified as a passive foreign investment company, or a PFIC, in 2014 or any future year. If we are a PFIC for any taxable year, this could result in adverse U.S. federal income tax consequences to U.S. Holders.

Under the U.S. Internal Revenue Code of 1986, as amended, or Code, we will be a PFIC for any taxable year in which, after the application of certain “look-through” rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of “passive income,” or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, “passive income.” Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains. Whether we will be a PFIC in any year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. Because (i) we currently own, and will own after the completion of this offering, a substantial amount of passive assets, including cash, and (ii) the values of our assets, including our intangible assets, that generate non-passive income for PFIC purposes, is uncertain and may vary substantially over time, it is uncertain whether we will be or will not be a PFIC in 2014 or any future year.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined below) holds ordinary shares, a U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition or dividends as ordinary income, (ii) the application of a deferred interest charge on such income, and (iii) compliance with certain reporting requirements.

For further discussion of the adverse U.S. federal income tax consequences of our classification as a PFIC, see “Taxation – U.S. federal income tax considerations for U.S. holders.”

Risks Related to Danish Law and Our Operations in Denmark

Preemptive rights may not be available to non-Danish shareholders, and any inability of non-Danish shareholders to exercise preemptive rights in respect of shares issued in any offering by us will cause their proportionate interests to be diluted.

Under Danish law, existing shareholders will have preemptive rights to participate on the basis of their existing share ownership in the issuance of any new shares for cash consideration, unless those rights are waived by a resolution of the shareholders or the shares are issued pursuant to an authorization granted to the board of directors including a waiver of preemptive rights. The preemptive rights of the shareholders may be waived by a majority comprising at least two-thirds of the votes cast and of the share capital represented at the general meeting provided the capital increase is made at market price. Certain non-Danish shareholders may not be able to exercise preemptive rights for their shares due to restrictions included in securities laws of certain countries, including those applicable in the United States. To the extent that shareholders are not able to exercise their preemptive rights in respect of the shares in any offering by us, such shareholders proportional interests will be diluted.

Upon the consummation of this offering, we will be a Danish public company with limited liability. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are, and will upon the consummation of this offering be, a Danish public company with limited liability. Our corporate affairs are governed by our Articles of Association and by the laws governing companies incorporated in Denmark. The rights of shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and boards of directors in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board is required by Danish law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. See “Description of Share Capital and Articles of Association – Corporate Governance.”

We are, as a foreign private issuer, not obligated to and do not comply with the all the corporate governance requirements of NASDAQ. This may affect your rights as a shareholder.

We will be a foreign private issuer for purposes of U.S. federal securities laws. As a result, in accordance with the listing requirements of NASDAQ, we will rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of NASDAQ. In accordance with Danish law and generally accepted business practices, our Articles of Association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of NASDAQ Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares. Although we must provide shareholders with an agenda and other relevant documents in advance of a general meeting of shareholders, Danish law does not have a regulatory regime for the solicitation of proxies, thus our practice will vary from the requirement of NASDAQ Listing Rule 5620(b). For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association – Corporate Governance.” Accordingly, you may not have the same protections afforded to shareholders of companies that are subject to these NASDAQ requirements.

As a Danish company we must comply with the Danish Companies Act, or DCA. The DCA contains binding provisions for the board of directors, shareholders and general meetings of shareholders; and financial reporting, auditors, disclosure, compliance and enforcement standards. Certain provisions apply to our board of directors (e.g., in relation to role, composition, conflicts of interest and independency requirements and remuneration), shareholders and the general meeting of shareholders (e.g., regarding our obligations to provide information to our shareholders). Further, certain sections of the DCA only apply to Danish companies listed on a regulated market with the EEA, and accordingly would not apply to us. See “Description of Share Capital and Articles of Association – Danish Corporate Governance.” This may affect your rights as a shareholder.

We have historically filed our Danish tax returns on a standalone basis; however, due to certain changes to the ownership structure of the company made at the start of 2013, as of January 2013, we must file our Danish tax returns as part of a Danish tax group controlled by Tech Growth Invest ApS, a Danish corporation (“Tech Growth”).

As of January 19, 2013, we became part of the tax group of Tech Growth for purposes of Danish law as a result of certain acquisitions made (see the table set forth in the section entitled “Principal Shareholders”). The relative responsibilities of Forward Pharma and the other members of the tax group are set forth in our Shareholders’ Agreement. Danish law provides for joint income taxation for all Danish entities in the same tax group, with the result that losses by one entity would be offset by gains by another. However, Danish law requires entities in the same tax group to pay each other for the use of each other’s tax losses. Therefore, any use of Forward Pharma’s losses by other members of the Tech Growth tax group will result in compensation to Forward Pharma.

All members of a Danish tax group are jointly and severally liable for the group’s Danish tax liabilities. However, Danish law requires taxing authorities to look primarily to Tech Growth and its wholly owned entities to satisfy Danish tax liabilities and to look to partially owned entities (such as Forward Pharma) only on a secondary basis. While we do not believe Tech Growth to have any material Danish tax liabilities, there can be no assurance that they do not have any such material liabilities, that they will not incur such material liabilities in the future, or that they will fulfill any such obligations. If Tech Growth has material Danish tax liabilities that are not satisfied by Tech Growth and its wholly owned subsidiaries or if Tech Growth incurs any such liabilities in the future, we may be responsible for the payment of such taxes, which could have an adverse effect on our results of operations.

We are adjusting our Danish tax returns to account for certain intangibles from the Aditech Patent Transfer Agreement we completed in 2010.

In 2010, we acquired intellectual property rights related to the development of our product candidate FP187 from Aditech. Danish law requires us to calculate the net present value of the future payments to be made to Aditech as remuneration for the rights acquired. The net present value is the basis for the amortization of such intangibles, which may be amortized over a period of seven years beginning with the year of purchase. We did not calculate the net present value of the future payments in connection with the acquisition of the rights related to FP187 and we have not taken any such amortization deductions as of this date. We are currently working with our Danish tax advisors to adjust our Danish tax returns as required. Although we do not anticipate any material tax liabilities will result from any such adjustments, there can be no assurances there will be no additional tax liabilities or that any additional liabilities will not be material.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Denmark. Substantially all of our assets are located outside the United States. The majority of our directors immediately following consummation of the offering reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

The United States and Denmark do not have a treaty providing for reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Accordingly, a final judgment for the payment of money rendered by a United States court based on civil liability will not be directly enforceable in Denmark. However, if the party in whose favor such final judgment is rendered brings a new lawsuit in a competent court in Denmark, that party may submit to the Danish court the final judgment that has been rendered in the United States. A judgment by a federal or state court in the United States will neither be recognized nor enforced by a Danish court, but such judgment may serve as evidence in a similar action in a Danish court.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors, officers or certain experts named herein who are residents of Denmark or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

We will be a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

CAUTIONARY STATEMENTS REGARDING FORWARD-LOOKING STATEMENTS

This Prospectus contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this Prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “may,” “should,” “plan,” “intend,” “estimate,” “will,” “would,” and “potential,” among others.

Forward-looking statements appear in a number of places in this Prospectus and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled “Risk Factors” in this Prospectus. These risks and uncertainties include factors relating to:

- statements regarding the timing of initiation and completion of the trials and when results of the trials will be made public;
- the clinical utility of FP187;
- the timing or likelihood of regulatory filings and approvals;
- our expectations regarding our planned path for approval of FP187 to treat RRMS, including the possibility that the FDA may determine that a single Phase 3 trial is insufficient for the approval of FP187 for RRMS;
- our estimates regarding the market opportunity for other indications for FP187;
- our ability to establish sales, marketing and distribution capabilities;
- our ability to establish and maintain manufacturing arrangements for FP187;
- our ability to enter into strategic relationships or collaborations with respect to FP187;
- our intellectual property position;
- our expectations regarding the use of proceeds from this offering;
- our estimates regarding expenses, future revenues, capital requirements and the need for additional financing;
- the impact of government laws and regulations;
- our competitive position;
- our ability to continue as a going concern; and
- other risk factors discussed under “Risk Factors.”

Forward-looking statements speak only as of the date they are made, and except as required by law, we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We prepare our consolidated financial statements in accordance with IFRS as issued by the IASB. None of the financial statements included in this Prospectus were prepared in accordance with generally accepted accounting principles in the United States.

The audited consolidated financial statements as of December 31, 2013 and 2012 and January 1, 2012 and for each of the two years in the period then ended are the audited consolidated financial statements for Forward Pharma A/S.

The terms “\$” and “USD” refer to U.S. dollars, the terms “DKK” and “Danish Kroner” refer to the legal currency of Denmark and the terms “€”, “EUR” and “Euro” refer to the legal currency of the euro area.

USE OF PROCEEDS

We expect to receive total estimated net proceeds of approximately \$, based on the midpoint of the estimated price range set forth on the cover of this Prospectus, after deducting estimated underwriting discounts and commissions and expenses of this offering that are payable by us. If the underwriters exercise their over-allotment option in full, we estimate that the net proceeds from this offering will be approximately \$, after deducting estimated underwriting discounts and commissions and expenses of this offering that are payable by us. Each \$1.00 increase (decrease) in the public offering price per ordinary share would increase (decrease) our net proceeds, after deducting estimated underwriting discounts and commissions and expenses of this offering that are payable by us, by \$, assuming that the number of shares offered by us, as set forth on the cover of this Prospectus, remains the same.

As of December 31, 2013, we had cash and cash equivalents of \$3.0 million. We currently expect that we will use the net proceeds from this offering, together with a bridge financing we expect to enter into prior to the completion of this offering, and cash and cash equivalents on hand, as follows:

- approximately \$90.0 million for the clinical development of FP187 for the treatment of RRMS;
- approximately \$30.0 million for the clinical development of FP187 for the treatment of psoriasis;
- approximately \$25.0 million to fund the exploitation and protection of our intellectual property rights (including in connection with oppositions and interference cases); and
- the remainder for working capital and other general corporate purposes, including execution of our pre-clinical program.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this Prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, pre-clinical and clinical development programs and whether we enter into collaborations with third parties in the future. As a result, management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds of this offering. In addition, we might decide to postpone or not pursue other clinical trials or pre-clinical activities if the net proceeds from this offering and our other sources of cash are less than expected.

Based on our planned use of the net proceeds of this offering, our expectations that we will enter into a bridge financing, which may be convertible into or exchangeable for a class of equity securities, and our current cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be incorrect, and we could exhaust our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing obligations and certificates of deposit.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our Class A shares or Class B shares, and we do not anticipate paying any cash dividends on our Class A shares or Class B shares or, following the Share Conversion, our ordinary shares, in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors (subject to shareholder approval) and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

CAPITALIZATION

The table below sets forth our capitalization (defined as total debt and shareholders' equity) as of December 31, 2013 derived from our consolidated financial statements included in this Prospectus:

- on an actual basis;
- on a pro forma basis reflecting the (a) issuance of 8,841 Class B shares on March 13, 2014 at a subscription price of DKK 1,177.35 per share; (b) issuance of 137,750 Class A shares on March 17, 2014 upon the cancellation of a convertible shareholder loan, the principal amount outstanding of which was used to offset the exercise price for 137,750 warrants to purchase Class A shares at a subscription price of DKK 100 per share; and (c) issuance of 260 additional Class A shares by way of exercise of 260 warrants at a subscription price of DKK 100 per share; and
- on a pro forma as adjusted basis, further reflecting (a) the automatic conversion of all of our Class A shares and Class B shares into ordinary shares pursuant to a Framework Agreement prior to consummation of this offering, and (b) the issuance and sale by us of _____ ordinary shares in this offering, at an assumed initial public offering price of \$ _____ per share, the midpoint of the price range set forth on the cover page of this Prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted column below is illustrative only, and our capitalization following completion of this offering will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing.

Investors should read this table in conjunction with our audited consolidated financial statements included in this Prospectus as well as "Use of Proceeds," "Selected Financial Information" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(USD in thousands)	December 31, 2013		Pro Forma (as adjusted)(1)
	Actual (audited)	Pro Forma	
Cash and cash equivalents	2,955		
Short-term convertible debt	2,613		
Long-term convertible debt, excluding current portion	0		
Total debt	2,613		
Share capital	287		
Share premium	26,697		
Total shareholders' equity	(26,415)		
Total capitalization(2)	(23,802)		

(1) Each \$1.00 increase (decrease) in the offering price of our ordinary shares would increase (decrease) our cash and cash equivalents, total shareholders' equity and total capitalization by \$ _____.

(2) Total capitalization consists of total debt plus total shareholders' equity.

DILUTION

If you invest in our ordinary shares, your interest will be diluted to the extent of the difference between the initial public offering price per share and the net tangible book value per share after this offering.

At December 31, 2013, we had a net tangible book value of \$(26.4 million), corresponding to a net tangible book value of \$ _____ per ordinary share, after giving pro forma effect to the Share Conversion. Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by _____, the total number of ordinary shares that would have been outstanding as of December 31, 2013 had the Share Conversion been effected on such date.

After giving effect to the sale by us of the _____ ordinary shares offered by us in this offering, and given an assumed initial public offering price of \$ _____ per share (which is the midpoint of the price range set forth on the cover of this Prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma net tangible book value estimated at December 31, 2013 would have been approximately \$ _____, representing \$ _____ per share. This represents an immediate increase in net tangible book value of \$ _____ per share to existing shareholders and an immediate dilution in net tangible book value of \$ _____ per share to new investors purchasing shares in this offering. Dilution for this purpose represents the difference between the price per share paid by these purchasers and net tangible book value per share immediately after the completion of this offering.

The following table illustrates this dilution to new investors purchasing shares in this offering.

	USD
Net tangible book value per share at December 31, 2013	
Increase in net tangible book value per share attributable to new investors	
Pro forma net tangible book value per share after the offering	
Dilution per ordinary share to new investors	
Percentage of dilution in net tangible book value per ordinary share for new investors	%

Each \$1.00 increase (decrease) in the offering price per share would increase (decrease) the pro forma net tangible book value after this offering by \$ _____ per share and the dilution to investors in the offering by \$ _____ per share.

The following table sets forth, on a pro forma basis as of December 31, 2013, after giving effect to this offering, the total number of shares owned by existing shareholders and to be owned by new investors, the total consideration paid and the average price per share paid by our existing shareholders and to be paid by new investors purchasing shares in this offering. The calculation below is based on an assumed initial public offering price of \$ _____ per share (which is the midpoint of the price range set forth on the cover of this Prospectus), before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

	Shares purchased		Total consideration		Average
	Number	Percent	Amount	Percent	price per share
Existing shareholders		%	\$	%	\$
New investors		%	\$	%	\$
Total		100%			

Each \$1.00 increase (decrease) in the offering price per share, respectively, would increase (decrease) the total consideration paid by new investors by \$ _____ million and increase (decrease) the percentage of total consideration paid by new investors by approximately _____ %, assuming that the number of shares offered by us, as set forth on the cover page of this Prospectus, remains the same.

The table above is based on our Class A shares and Class B shares outstanding as of December 31, 2013, assuming the conversion of all such shares into ordinary shares pursuant to the Share Conversion. The table above does not include:

- 139,733 of our Class A shares issuable upon the exercise of warrants outstanding as of December 31, 2013 at a weighted average exercise price of DKK 151.05 per share; and
- Exercise by the underwriters of their over-allotment option; if the over-allotment option is exercised in full, the following will occur:
 - the percentage of our ordinary shares held by existing shareholders will decrease to approximately _____ % of the total number of our ordinary shares outstanding after this offering; and
 - the percentage of our ordinary shares held by new investors will increase to approximately _____ % of the total number of our ordinary shares outstanding after this offering.

SELECTED FINANCIAL INFORMATION

The summary statement of profit or loss and statement of financial position for the years ended and as of December 31, 2013 and 2012 of Forward Pharma A/S are derived from the consolidated financial statements included in this Prospectus. We prepare our consolidated financial statements in accordance with IFRS as issued by the IASB.

This financial information should be read in conjunction with “Presentation of Financial and Other Information,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements, including the notes thereto, included in this Prospectus.

Consolidated statement of profit or loss data

(USD in thousands, except share and per share data)	Year ended December 31,	
	2013	2012
Research and development costs	(8,018)	(4,445)
General and administrative costs	(1,014)	(928)
Operating loss	(9,032)	(5,373)
Fair value adjustment to net settlement obligations to shareholder warrants	(6,676)	(17,071)
Other finance costs	(84)	(35)
Net losses before tax	(15,792)	(22,479)
Income tax	96	0
Net losses for the year	(15,696)	(22,479)
Net loss per share		
Basic and diluted	(9.53)	(14.25)
Weighted-average shares outstanding used to calculate net loss per share		
Basic	1,598,530	1,577,261
Diluted	1,598,530	1,577,261

Consolidated statement of financial position data

(USD in thousands)	As of December 31,	
	2013	2012
Cash and cash equivalents	2,955	828
Adjusted working capital (1)	2,317	213
Total assets	3,599	970
Long-term debt, including current portion	2,613	2,100
Accumulated deficit	(51,913)	(36,796)
Total shareholders’ equity	(26,415)	(20,250)

- (1) We define adjusted working capital as current assets minus trade and other payables. We use adjusted working capital to, among other things, evaluate our short-term liquidity requirements. We find adjusted working capital a useful metric in evaluating our short-term liquidity requirements because it eliminates the impact of shareholder warrants.

Adjusted working capital is not a U.S. GAAP or IFRS measure, and our definition may vary from that used by others in our industry. Accordingly, our use of adjusted working capital has limitations as an analytical tool and you should not consider it in isolation or as a substitute for analysis of our financial position as reported under IFRS.

EXCHANGE RATE INFORMATION

Our business is primarily conducted in Denmark and Germany. The functional currency of Forward Pharma A/S is the Danish Kroner and the functional currency of Forward Pharma GmbH is the Euro, although Forward Pharma A/S reports its consolidated financial statements in U.S. dollars. Certain information in this Prospectus is presented in Danish Kroner. On March 31, 2014, the exchange rate was DKK 5.417 to \$1.00.

The following table presents information on the exchange rates between the Danish Kroner and the U.S. dollar for the periods indicated, as published by the Danish Central Bank.

	Period- end	Average for Period (DKK per USD)	Low	High
Year Ended December 31:				
2009	5.186	5.355	4.931	5.946
2010	5.555	5.625	5.115	6.234
2011	5.725	5.357	5.008	5.760
2012	5.659	5.794	5.523	6.156
2013	5.414	5.618	5.400	5.833
Month Ended:				
November 2013	5.478	5.530	5.478	5.587
December 2013	5.414	5.444	5.400	5.503
January 2014	5.533	5.477	5.414	5.533
February 2014	5.486	5.468	5.404	5.529
March 2014	5.417	5.398	5.434	5.359

The following table presents information on the exchange rates between the Euro and the U.S. dollar for the periods indicated, as published by WM/Reuters.

	Period- end	Average for Period (EUR per USD)	Low	High
Year Ended December 31:				
2009	0.697	0.719	0.798	0.663
2010	0.745	0.755	0.838	0.687
2011	0.770	0.719	0.774	0.672
2012	0.758	0.778	0.827	0.743
2013	0.726	0.753	0.782	0.724
Month Ended:				
November 2013	0.734	0.741	0.749	0.734
December 2013	0.726	0.730	0.738	0.724
January 2014	0.742	0.734	0.742	0.726
February 2014	0.724	0.732	0.740	0.724
March 2014	0.726	0.723	0.728	0.718

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the information under "Selected Financial Information" and our consolidated audited financial statements, including the notes thereto, included in this Prospectus. The following discussion is based on our consolidated financial information prepared in accordance with IFRS as issued by the IASB, which might differ in material respects from generally accepted accounting principles in other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Risk Factors" and elsewhere in this Prospectus.

Overview

Forward Pharma is a Danish biopharmaceutical company preparing to initiate a Phase 3 clinical trial using FP187, a proprietary formulation of dimethyl fumarate, or DMF, for the treatment of multiple sclerosis, or MS, patients. Since our founding in 2005, we have worked to advance unique formulations of DMF, an immune modulator, as a therapeutic to improve the health and well-being of patients with immune disorders including MS. FP187, our clinical candidate, is a DMF formulation in an oral dose that employs both matrix and delayed release technologies to control drug release which we plan to advance for the treatment of relapsing remitting MS, or RRMS, and other immune disorders, such as psoriasis.

We are a company with a limited number of employees and outsource the majority of our activities to external consultants and suppliers. We are comprised of a Danish incorporated parent company, Forward Pharma A/S, and a wholly-owned subsidiary incorporated in Germany, Forward Pharma GmbH.

Trend Information

We do not currently have any commercialized products on the market. Accordingly, any trends within the markets in which we operate are expected to have more direct impact on our business in the event that we are successful in commercializing our clinical candidate FP187.

Over the past few years, there has been increasing pressure to reduce drug prices in the developed markets as a consequence of political initiatives and regulations aiming to curb continuous increases in healthcare spending. Any revenue we earn in the future may be negatively affected by such political initiatives and regulations. The financial recent crisis and the increased burden of healthcare costs have led to an increased focus on reducing costs and, therefore, have further increased the pressure to lower drug prices. We expect this trend to continue in the years ahead. However, we believe spending in the healthcare industry, as compared to many other industries, is less linked to economic trends. Furthermore, while falling drug prices in the mature drug markets such as the U.S. and the EU are having a negative impact on general sales growth levels for the biopharmaceutical industry as a whole in those markets, we expect such sales growth to continue at higher levels in emerging markets. We also expect that demographic developments, increased treatment penetration, especially in newly established drug markets, and better diagnostic tools to enable the tailoring of drugs to specific needs, will result in continuing growth in overall global drug sales.

There are unmet medical needs both in the RRMS and psoriasis areas. In particular, products with positive long-term safety profiles are needed. Controlling side effects associated with many such drugs is also important. Improvements have been seen in biological treatments for both RRMS and psoriasis, but there remains a need for safe oral treatments for both indications for long-term chronic administration. We believe that DMF has the potential to fulfill such unmet needs.

Financial Operations Overview

Revenue

To date, we have not generated any operating revenue as we do not have any commercialized products and we have not out-licensed our clinical candidate FP187 to any third-party.

Research and development costs

Research and development costs consist primarily of:

- salaries for research and development staff and fees to consultants, as well as expenses incurred by all such personnel; expenses related to share-based compensation to employees and others; the costs of our extensive use of external third-party expert and advisory firms and personnel for our product development efforts; and the outsourcing of specific development tasks to contract manufacturing organizations, or CMOs;
- costs for formulation, development and production of FP187 tablets in new doses for use in clinical trials; and production of DMF by our current external single-source CMO, including the costs of testing related to increasing the batch sizes and manufacturing capability of this CMO in order for us to be able to scale to anticipated commercial production levels;
- fees and other costs paid to clinical research organizations, or CROs, in connection with additional pre-clinical testing, formulation and product testing of FP187; and the fees and costs associated with the performance of clinical trials in RRMS and psoriasis, which will be outsourced as full service projects to CROs, which will plan and run the clinical trials for us, and help us to gather and maintain all required clinical data for regulatory purposes; and
- filing, prosecuting, and defending patent claims and other intellectual property rights (including patent opposition and interference proceedings).

All of our operational activities are initiated, conducted and overseen by staff at our German subsidiary in Leipzig and, as a result, the majority of our development costs are incurred by our German subsidiary.

We expect that our total research and development costs in 2014 will be approximately \$32.0 million, assuming completion of the anticipated bridge financing and successful consummation of this offering. Our research and development costs relate primarily to the following key programs:

- development of our FP187 program for RRMS, including the preparation of a Phase 3 clinical trial protocol, establishment of related databases and data capturing systems, and preparation of regulatory submissions, all of which is being coordinated for us by a CRO and is planned for the second half of 2014;
- the launch of a Phase 3 clinical trial program for FP187 in psoriasis, with the expected initiation of patient dosing in Europe in 2014 and preparation for the U.S. Phase 3 clinical trial, along with further related Phase 1 clinical trials;
- continuation of a pre-clinical test program for FP187 including short reproduction studies and long term carcinogenicity tests;
- development of new tablet strengths and formulations of FP187 for RRMS and psoriasis, and working with our CMOs to increase DMF production processes and FP187 batch size levels and related manufacturing capability in order for us to be able to scale to anticipated commercial production levels;
- technology transfer in connection with our efforts to secure secondary CMO partners for DMF and FP187 production;
- follow up on our IND submission for RRMS and any FDA-related requests involving such IND;
- Phase 3 clinical trial protocol development and discussions with CROs and clinical advisers for the RRMS indication, and submission of the protocol following our IND filing with the FDA; and
- filing, prosecuting, and defending patent claims and other intellectual property rights (including patent opposition and interference proceedings).

In 2013 and 2012, we spent an aggregate of \$8.0 million and \$4.4 million, respectively, on research and development. Our research and development costs may vary substantially from period to period based on the timing of our research and development activities, including timing of regulatory approvals and enrollment of patients in clinical trials, and the preparation and submission of new patent claims in the U.S. Research and development costs are expected to increase as we advance the clinical development of FP187 into Phase 3 for RRMS and psoriasis. The successful development of FP187 is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which we may begin to recognize revenues from FP187. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of the scope, rate of progress and expense of:

- our research and development activities;
- clinical trial approvals, securing sufficient clinical trial sites, recruitment of subjects for our clinical trials in a timely manner, and completion of the clinical trials;
- regulatory activities, including agency meetings, dossier preparations and submissions;
- any further pre-clinical or clinical studies that we may initiate; and
- prosecuting and defending patent claims and other intellectual property rights (including patent opposition and interference proceedings).

A change in the outcome of any of these factors with respect to the development of FP187 or any other product that we may develop could result in a significant change in the costs and timing associated with the development of FP187 or such other products.

Similarly the preparation of the Phase 3 trial of FP187 for the treatment of RRMS is a major effort and will require substantial internal resources and cooperation with a global CRO. We are in the early stages of such planning and further development depends on the positive outcome of this offering.

If litigation with respect to our intellectual property rights were to commence, or if we were to become subject to other type of litigation, the magnitude and timing of our estimated costs could materially change.

General and administrative costs

Our general and administrative costs consist primarily of:

- salaries and expenses for employees other than research and development staff, as well as expenses related to share-based compensation awards granted to certain employees;
- professional fees for auditors and other consulting expenses not related to research and development activities;
- cost of facilities, communication and office expenses; and
- information technology, or IT, related expenses.

We expect that our general and administrative costs will increase in the future as our business expands and we incur additional costs associated with operating as a public company. This will include costs related to retaining personnel to establish a finance department and upgrading our financial and financial reporting processes in Germany and Denmark, as well as engaging investor relations firms for both the U.S. and the EU. The impact of us becoming a public company will also include increased costs related to new personnel we will need to retain in connection with both administrative and operational activities, legal compliance fees, accounting and audit fees, board of directors and board of managers' liability insurance premiums, and costs related to general investor relations. In addition, we may incur costs associated with granting share-based compensation awards to key management personnel and other employees after this offering.

Finance cost (net)

Components of our finance cost (net) during 2013 and 2012 consisted primarily of:

- fair value of gains / losses on net settlement obligations related to shareholder warrants; and
- interest expenses on debt obligations (consisting of a convertible debt instrument, which has now converted into equity).

Results of Operations

Comparison of the years ended December 31, 2013 and 2012

	Year ended December 31,		Change
	2013	2012	%
	(USD in thousands)		
Total revenue	0	0	0
Research and development costs	(8,018)	(4,445)	80.4
General and administrative costs	(1,014)	(928)	9.3
Operating loss	(9,032)	(5,373)	68.1
Fair value adjustment to net settlement obligations to shareholder warrants	(6,676)	(17,071)	(60.9)
Other finance costs	(84)	(35)	140.0
Finance cost (net)	(6,760)	(17,106)	(60.5)
Net loss before tax	(15,792)	(22,479)	(29.7)

Research and development costs for the years ended December 31, 2013 and 2012

Research and development costs increased 80.4% to \$8.0 million in the year ended December 31, 2013, from \$4.4 million in the year ended December 31, 2012. Our research and development costs are highly dependent on the development phases of our projects and therefore fluctuate significantly from year to year.

The increase in research and development costs from 2012 to 2013 related to the re-initiation in 2013 of a number of development activities within both pharmaceutical and clinical development. This included production of new batches of DMF and validation of the production, development activities related to the production of FP187 tablets, the purchase of comparator and placebo tablet production for the Phase 3 clinical program in psoriasis, and the submission of materials in connection with, and preparation for, our planned Phase 3 psoriasis clinical trial program. We expect that our total research and development costs in 2014 will be approximately \$32.0 million, assuming completion of the anticipated bridge financing and successful consummation of this offering. The increase in such costs is expected to be primarily the result of pursuing the Phase 3 trial for FP187 for the treatment of RRMS, but also includes significant costs related to the Phase 3 trial program for FP187 for the treatment of psoriasis.

General and administrative costs for the years ended December 31, 2013 and 2012

General and administrative costs increased to \$1.0 million in the year ended December 31, 2013 from \$928,000 in the year ended December 31, 2012, due to business development initiatives and costs related to managing and maintaining our intellectual property, as well as increased travel by our employees. We anticipate that our general and administrative costs will increase in the future as we continue to pursue our clinical development program and we incur additional costs associated with operating as a public company, including the addition of an expanded finance team. We also anticipate our administrative costs will increase due to significant upgrades in our IT systems and IT security associated with our becoming a public company.

Finance costs for the years ended December 31, 2013 and 2012

Finance costs related to the fair value adjustment to net settlement obligations of our shareholder warrants decreased to \$6.7 million in 2013, from \$17.1 million in 2012. This decrease was due primarily to the fact that the underlying share price increased substantially more in 2012 than it did in 2013. Finance costs associated with the shareholder warrants are calculated by multiplying the number of shares underlying the outstanding shareholder warrants by the fair value of such shares, and subtracting the applicable exercise price.

Other finance costs consisted of interest on convertible debt (which has now converted to equity) and other financial expenses, and amounted to \$84,000 in 2013 and \$35,000 in 2012.

Liquidity and Capital Resources

To date, we have financed our operations through shareholder investments in the form of and equity and convertible debt financings. Discussions with certain of our existing shareholders with respect to a possible bridge financing are ongoing and, if successful, we believe will secure the company as a going concern, although, absent the success of the proposed offering, requiring a lower overall business activity level. For more, see “Cash and funding sources.”

Cash flows

Comparison of the years ended December 31, 2013 and 2012

Our cash and cash equivalents as of December 31, 2013 were \$3.0 million. The table below summarizes our consolidated statement of cash flows for each of the years ended December 31, 2013 and 2012:

	Year ended December 31,	
	2013	2012
	(USD in thousands)	
Net cash flows used in operating activities	(8,373)	(3,494)
Net cash flows used in investing activities	0	(5)
Net cash flows from financing activities	10,397	3,885
Net increase in cash and cash equivalents	2,024	386
Cash and cash equivalents at December 31	2,955	828

Net cash flows used in operating activities increased to \$8.4 million in the year ended December 31, 2013, from \$3.5 million in the year ended December 31, 2012, primarily due to an increase in research and development costs as described in the section above entitled “Research and development costs for the years ended December 31, 2013 and 2012.”

The net cash flows used in investing activities decreased to zero in the year ended December 31, 2013, from \$5,000 in the year ended December 31, 2012.

Net cash flows from financing activities increased by 167.6% to \$10.4 million in the year ended December 31, 2013, from \$3.9 million in the year ended December 31, 2012. This increase was due primarily to our issuance of 37,874 Class B shares in 2013 for net proceeds of \$8.0 million in cash.

Cash and funding sources

The table below summarizes our sources of financing and related cash proceeds for the years ended December 31, 2013 and 2012.

	Year ended December 31,	
	2013	2012
	(USD in thousands)	
Equity capital	7,951	1,864
Shareholder loans	2,456	2,030
Net settlement obligations to shareholder warrants	26,124	18,370

In 2013, we issued a convertible loan to one of our shareholders with a principal value of \$2.5 million, which was converted into shares in March 2014. In 2012, we also issued a convertible loan to one of our shareholders, which was converted into equity in January 2013.

In 2013, we issued to one of our existing shareholders 37,874 Class B shares for \$8.0 million in cash. In 2012, we issued to one of our shareholders 71,618 Class A shares for \$1.9 million in cash.

Net settlement obligation to shareholder warrants reflect the fair value of the warrants outstanding as of the respective balance sheet dates and will, on exercise or lapse, result in a reclassification from liabilities to equity.

We are currently involved in discussions related to a potential bridge financing. While we anticipated entering into such facility, we have not received a commitment or entered into a term sheet in respect of the bridge financing, and therefore there can be no assurance we will be able to secure such financing.

Please refer to the sections below on “Funding requirements” and “Borrowings” for a discussion of the significant assumptions underlying our going concern assumption.

Funding requirements

We believe that the net proceeds from this offering, together with the proposed bridge financing and our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. We have no ongoing material financial commitments, such as lines of credit or guarantees, which are expected to affect our liquidity over the next five years, other than office rental leases, which we consider immaterial.

Our present and future funding requirements will depend on many factors, including, among other things:

- our product development and increasing production capacity to commercial scale;
- technology transfer in connection with our efforts to identify additional CMOs;
- the scope and timing of our pre-clinical and clinical testing programs;
- successful planning and implementation of the required clinical development programs for FP187, particularly for the RRMS indication, but also for the planned psoriasis indication;
- our establishment of an internal organization and structure needed for a public company, including the hiring of additional personnel and developing appropriate policies and procedures; and
- our ability to continue as a going concern.

Our ability to operate is dependent upon raising additional funds to finance our ongoing activities. According to our estimates, based on our budget, if we are unsuccessful in obtaining additional capital resources to maintain our operational activities, there is substantial doubt that we will be able to continue our ongoing activities until December 31, 2014. In addition to pursuing this offering, we anticipate entering into a bridge financing.

In the event that we are unable to secure the potential bridge financing that we currently are pursuing, or in the event we are unable to consummate this offering on the terms we currently anticipate or at all, we will have to limit our research and development activities until we are able to obtain alternative funding sources.

Capital Expenditures

Our capital expenditures were zero for the year ended December 31, 2013, and \$5,000 for the year ended December 31, 2012.

Contractual obligations and commitments

The table below sets forth our contractual obligations and commercial commitments as of December 31, 2013.

	Payments due by period				Total
	Less than 1 year	Between 1 and 2 years	Between 2 and 5 years	More than 5 years	
	(USD in thousands)				
Debt obligations(1)	\$2,613	\$0	\$0	\$0	\$2,613
Operating lease obligations(2)	\$21	\$0	\$0	\$0	\$21
Total	\$2,634	\$0	\$0	\$0	\$2,634

(1) Debt obligations as of December 31, 2013 consisted of a convertible loan note dated October 1, 2013, by and between Forward Pharma, as debtor, and Nordic Biotech Opportunities Fund K/S, as creditor, for a principal amount of \$2.5 million, which was cancelled in March 2014 (in connection with which the principal amount was used to offset the exercise price of warrants to purchase an aggregate of 137,500 Class A shares at an exercise price of DKK per share). The loan was to mature on October 31, 2018 and had an annual interest rate of 20% as of December 31, 2013.

(2) Operating lease obligations consist of a rental property agreement.

Off-Balance Sheet Arrangements

In 2004, a private Swedish company Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech Advisors (an affiliate of one of our largest shareholders), began developing and filing patents for an innovative formulation and delivery system for DMF. In 2005 Forward Pharma A/S entered into a patent license agreement with Aditech to license this patent family from Aditech, and in 2010 we acquired this patent family from Aditech pursuant to a patent transfer agreement. Under the agreements with Aditech, we obtained, among other things, Aditech's patents and associated know-how related to DMF formulations and delivery systems, subject to both diligence and minimum annual expenditure of €1.0 million (approximately \$1.4 million) obligations on our part (with an option for Aditech to receive back, for no consideration, all of the DMF related assets should we fail to satisfy such obligations), as well as a payment by us to Aditech of up to 2% of net sales generated from our DMF products and processes. Further, the agreement with Aditech gives Aditech a 90-day right of first offer to acquire non-DMF related intellectual property assets that we might choose to sell.

A German government grant of approximately \$5.2 million received by us as compensation for development costs we incurred must be repaid by us should SAB determine that the grant was not, or not entirely, used for the specific purpose of the project for which it was given. In June 2012, SAB concluded the proceedings of proof of correct use, retaining, however a right to initiate further proceedings. Further, if a production site has not been established by us in Saxony by May 31, 2017, this grant shall be repaid with a share in the income generated by us from the exploitation of the results, pro rata, up to a maximum of the grant amount, plus interest, if applicable. Should we not comply with this obligation, we will be required to grant SAB rights of use regarding the results of the funded research. As of December 31, 2013, we had not decided whether to establish production facilities in Saxony. Further, we believe that as

of December 31, 2013, there is uncertainty in respect of both future revenue from the development project and the possible proceeds from a sale of all or certain of our intellectual property rights if we were to cease development. On this basis, we have determined that it is currently appropriate not to recognize as a contingent liability the repayment of this German government grant.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to a variety of financial risks: market risk (including foreign exchange risk and interest rate risk), credit risk and liquidity risk. See note 4.2 to the Consolidated Financial Statements included in this Prospectus.

Market risk

We are exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. dollar, British pound sterling, or GBP, and the Euro.

Forward Pharma A/S' functional currency is the Danish Kroner, or DKK, and our subsidiary Forward Pharma GmbH's functional currency is the Euro. We anticipate that a substantial portion of any revenue earned as sales of goods or royalty payments following the commercialization of FP187 will be denominated in either U.S. dollars or Euro. Our expenses to date have been largely denominated in GBP, USD, DKK, and in Euro.

In accordance with IFRS, at period end all of Forward Pharma A/S' and Forward Pharma GmbH's assets and liabilities denominated in foreign currencies are recorded in the financial statements in DKK and Euro respectively, using exchange rates in effect at the applicable balance sheet date. During the year, transactions in foreign currencies are recorded in DKK and Euro respectively at the applicable exchange rates on the date of the relevant transactions.

We do not believe there is currently a need to enter into specific contracts to reduce the exposure to changes in foreign exchange rates, such as by entering into options or forward contracts. We may in the future consider using options or forward contracts to manage currency transaction exposures. To date, we have had no material financial impact as a result of foreign currency changes.

During 2013 and 2012, our borrowings were denominated in DKK. Because our borrowings were at fixed interest rates and we maintain only limited cash balances, a change in interest rates would not have had a material effect on our results of operations.

Credit Risk

We manage credit risk on a group basis.

Our cash and cash equivalents are invested primarily in saving and deposit accounts with original maturities of three months or less. Saving and deposit accounts generate a small amount of interest income. For banks and financial institutions, only independently rated parties with a minimum rating of 'A' are used by us.

Government, Economic, Fiscal, Monetary or Political Initiatives That May Materially Affect Our Operations

We have not identified any current government, economic, fiscal, monetary or political initiatives that would be expected to materially affect our operations.

Critical Accounting Policies

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which we have prepared in accordance with IFRS as issued by the International Accounting Standards Board. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements appearing elsewhere in this Prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

Research and development costs

Research expenses are recognized when expenses are incurred. Costs incurred on development projects will be recognized as intangible assets as of the date that it can be established that it is probable that we will recognize future economic benefits attributable to the relevant project, considering factors including the technological and commercial feasibility of the project. Specifically, intangible assets arising from our development projects will be recognized on our balance sheet if all of the following criteria are met:

- the development project is clearly defined and identifiable,
- the attributable costs can be measured reliably during the development period;
- the technological feasibility, adequate resources to complete and a market for the product or an internal use of the product can be demonstrated; and
- management has the intent to produce and market the product or otherwise utilize it.

Development costs incurred are capitalized as of the date when these criteria are met. In other words, until such criteria are met, development costs incurred are recognized as an expense.

A development project involves a single product candidate undergoing a high number of tests to illustrate its safety profile and the effect on humans prior to obtaining the necessary final approval of the product from the appropriate authorities. The future economic benefits associated with our individual development projects are dependent on obtaining such approval. Considering the significant risk and duration of the development period related to the development of biological products, management has concluded that the future economic benefits associated with FP187 in late-stage clinical development in RRMS and psoriasis individual projects cannot be estimated with sufficient certainty until the projects have been finalized and the necessary regulatory final approvals have been obtained. Accordingly, given the current stage of the development of FP187, no development expenditures have yet been capitalized.

Intellectual property-related costs for patents are included in expenses for our research and development projects. Therefore, associated registration costs for patents are expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

Share-based compensation

The fair value of warrants (the share-based compensation arrangement we have historically used) issued to our employees and consultants in connection with their services provided to us is recognized by us as compensation expenses over the applicable warrant vesting periods.

Determination of the initial fair value and subsequent compensation expenses for our warrants are subject to significant estimation uncertainty. For publicly traded entities, such fair value determinations are often calculated using an option valuation model, which relies on the publicly traded price of such public entity's shares and its expected volatility based in part on historical share price volatility. As a private company, this is not a valuation model that is easy for us to employ. Historically, we have been governed by a shareholders' agreement, which provided different liquidation preferences rights among our share classes and restricted the trading of our shares, resulting in no observable share volatility.

To enable us to use the option valuation model to determine fair value, for warrants granted through December 30, 2012 we established our share price at the date of each grant by assuming that we might be sold at a specified price per share, which was equivalent to the price per share paid in a financing round prior to the warrant grant date. Beginning on December 31, 2012, because a short time after that date we issued Class B shares with preferential rights, accompanied by warrants given to the purchasers of such Class B shares providing a right to subscribe for Class A shares, it was no longer possible to establish a price at which the Class A shares underlying our employee and consultant warrants would have been issued had we granted them on the same or near date as the Class B shares. Accordingly, starting on December 31, 2012, we determined our price per share using an estimation methodology. See "Valuation of shares" below.

Volatility of share price for a non-public company, like ours, was difficult to estimate. As a result, we opted to employ a Black-Scholes formula model, in which we assessed the volatility of the share prices of what we identified as a peer group of currently public biopharmaceutical companies.

Valuation of net settlement obligations to shareholder warrants

In 2011 we granted one of our shareholders warrants to acquire our Class A shares in connection with a capital increase made by such shareholder. This warrant provides that the holder can elect to exercise the warrant by net share settlement (also commonly referred to as a "cashless" exercise method) in which certain of the underlying Class A shares are used, based on their fair value, to pay the exercise price. This warrant is classified by us as a derivative financial instrument due to the fact that the holder can elect to employ the net share settlement means to pay the exercise price and, as a result, is recorded by us within our current liabilities on our statement of financial position.

Determination of fair value of our net settlement obligations to shareholder warrants is subject to significant estimation uncertainty. As discussed earlier, for publicly listed companies, fair value is generally calculated using option valuation models based on the trading price of the shares and expected volatility based in part on historical volatility of share prices. Because our shares are not traded in an active market, there is no observable market data to support our valuation. We applied the valuation approach describe dunder "Share-based compensation" above. As of December 31, 2013 and 2012, respectively, the exercise price of our shareholder warrants is significantly lower than the underlying share price as of each such date and, consequently, fair value of the warrants is most sensitive to changes in the underlying share price.

Valuation of shares

As of December 31, 2012, we have calculated our valuation based on an internal model we developed that considered each of what we believe to be our key value drivers, including intellectual property advancement, development stage of FP187 both in terms of manufacturing and regulatory advances, and commercialization prospects for FP187. More specifically, we considered numerous objective and subjective factors to determine our best estimate of the fair value of our shares as of each grant date, including the following:

- status of our intellectual property;
- progress of our research and development programs;
- costs necessary to complete Phase 3 programs for both RRMS and psoriasis;
- likelihood of successful completion of our Phase 3 programs for RRMS and psoriasis;

- likelihood of obtaining regulatory approvals for FP187 to treat each of RRMS and psoriasis;
- potential of commercial success taking into account the risk of competition from other market participants;
- market penetration and price structure in the markets where we expect to sell FP187;
- costs to establish a production site for FP187;
- the relative rights and preferences of our capital shares; and
- external market and economic conditions impacting our industry sector.

Our fair value as of December 31, 2012 has been determined by us through employing a discounted cash flow, or DCF, model. DCF is an estimate of the present value of the future monetary benefits expected to flow to the owners of a business. It requires a projection of the cash flow that the business is expected to generate. This cash flow is converted to present value by means of discounting, using a rate of return that accounts for the time value of money and the appropriate degree of risks inherent in the business. The discount rate in the DCF analysis is based upon a weighted average cost of capital, or WACC, calculated at each valuation date. The WACC is a method that market participants commonly use to price securities and is derived by using the Capital Asset Pricing Model and inputs such as the risk-free rate, beta coefficient, equity risk premiums and the size of the company. For our valuation as of December 31, 2013, a discount rate (WACC) of 12% has been applied, and for the valuation as of December 31, 2012, a rate of 10.9% has been applied.

The cash flow projections were based on probability-weighted scenarios which considered estimates of time to market of our products, market share and pricing. The estimated underlying cash flows were unchanged from 2012 to 2013.

We applied the following probabilities (%) for 2013 and 2012, respectively:

	2013	2012
• likelihood of exploiting our intellectual property	30	25
• likelihood of obtaining regulatory approval	50	50
• likelihood of commercial success	40	35

A discount for lack of marketability, or DLOM, of 25% and 25%, as of December 31, 2012 and December 31, 2013, respectively, was applied to reflect the increased risk arising from the inability to readily sell our shares.

Through December 30, 2012, we had only issued Class A shares, and the value of one share was determined with reference to the above described fair value of the Company divided by the number of outstanding shares, taking into account the dilutive effect of outstanding warrants, resulting in a price per share amount of \$150.

On January 19, 2013, we issued shares with liquidation preference. Our fair value calculated as of this point in time is allocated to the preferred shares and ordinary shares using the current value method, or CVM, and taking into account the dilutive effect of outstanding warrants. The CVM assumes an immediate exit of the company and allocates value to our preferred shares based on the liquidation preferences and the residual value to the remaining shares. Due to a limited absolute liquidation preference compared to the total value of the Company as of the respective valuation dates subsequent to issuance of preference shares, we did not apply an OPM. The OPM treats ordinary shares and preferred shares as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes.

Equity was allocated using the CVM, resulting in a value per share of \$137 as of January 19, 2013, and \$208 as of December 31, 2013. We determined that there had been no events intervening between the respective valuation dates and therefore the analysis and inputs remained the same.

IPO price versus last valuation

On _____, we and our underwriters determined the estimated price range for this offering, as set forth on the cover page of this prospectus. The midpoint of the price range is \$ _____ per share. In comparison, our estimate of the fair value of our ordinary shares was \$208 per share as of December 31, 2013. We note that, as is typical in initial public offerings, the estimated price range for this offering was not derived using a formal determination of fair value, but was determined by negotiation between us and the underwriters. Among the factors that were considered in setting this range were our prospects and the history of and prospects for our industry, the general condition of the securities markets and the recent market prices of, and the demand for, publicly traded shares of generally comparable companies. Specifically, we believe that the difference between the fair value of our ordinary shares as of December 31, 2013 and the midpoint of the estimated price range for this offering is primarily due to advances we have made in connection with our intellectual property, manufacturing and regulatory development, and commercialization prospects.

Income taxes

We are subject to income taxes in Denmark and Germany. Significant judgment is required in determining the use of net operating loss carry forwards and, were it to be applicable in our case, taxation of upfront and milestone payments (related to possible out-licensing transactions we might consider) for income tax purposes. There are many transactions and calculations for which the ultimate tax determination is uncertain. Where the final tax outcome of these matters is different from the amounts that were initially recorded, such differences will impact the current and deferred income tax assets and liabilities in the period in which such determination is made.

We recognize deferred tax assets, including the tax base of tax loss carry forwards, if our management assesses that these taxes can be offset against positive taxable income within a foreseeable future. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and level of future taxable profits together with future tax planning strategies. Such a judgment will be made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

The creation and development of therapeutic products, such as our product candidate FP187, is subject to considerable risks and uncertainties. Since our inception, we have reported significant losses and as a consequence, we have unused tax losses.

Our management has concluded that deferred tax assets should not be recognized as of December 31, 2013 or as of December 31, 2012 in accordance with IAS 12, "Income Taxes." Our tax assets are currently not deemed to meet the criteria for recognition as our management is not able to provide any convincing positive evidence that deferred tax assets should be recognized.

We had unused tax loss carry forwards of \$10.5 million in Denmark and \$17.8 million in Germany as of December 31, 2013. The unused tax carry forward losses in Denmark and Germany do not have an expiry date.

We are currently subject to group taxation in Denmark. For more, see “Risk Factors – Risks Related to Danish Law and Our Operations in Denmark – We have historically filed our Danish tax returns on a standalone basis; however, due to certain acquisitions made at the start of 2013, as of January 2013, we must file our Danish tax returns as part of a Danish tax group controlled by Tech Growth Invest ApS, a Danish corporation (“Tech Growth”).”

Borrowings

As of December 31, 2013, our borrowings consisted of a convertible shareholder loan with a principal value of DKK 13.8 million (\$2.5 million), which was scheduled to mature on October 31, 2018. The loan was cancelled in March 2014 in connection with which the principal amount outstanding was used to offset the exercise price of warrants to purchase an aggregate of 137,500 Class A shares at an exercise price of DKK per share.

We are currently involved in discussions related to a possible bridge financing, which we anticipate entering into prior to consummation of this offering. We have not received a commitment or entered into a term sheet in respect of such financing. We note that the expected bridge financing mentioned above is not linked to whether or not this offering is completed. Together with the assumptions disclosed in the section above entitled “Funding requirements”, the expected bridge financing forms a part of the basis for the going concern assumption reflected in this Prospectus.

Recent Accounting Pronouncements

There are no IFRS standards as issued by the IASB or interpretations issued by the IFRS interpretations committee that are effective for the first time for the financial year beginning on or after January 1, 2014 that would be expected to have a material impact on our financial position.

Internal control over financial reporting

In connection with the audits of our 2013 and 2012 financial statements which were completed concurrently, our independent registered public accounting firm identified a material weakness related to our financial statement close process, primarily related to the lack of sufficient skilled personnel with IFRS and SEC reporting knowledge for the purposes of timely and reliable financial reporting. Specifically, our independent registered public accounting firm determined that we did not have adequate procedures and controls to ensure that accurate financial statements could have been prepared and reviewed on a timely basis for annual and interim reporting purposes, including insufficient financial statement close process and procedures including account reconciliations, the resolution of complex accounting issues involving significant judgment and estimates and overall review of the financial statements.

Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We are working to remediate the material weakness and are taking numerous steps and plan to take additional steps to remediate the underlying causes of the material weakness. We are currently in the process of recruiting a full-time Chief Financial Officer, and plan to recruit additional finance support personnel and further develop and implement formal policies, processes and documentation procedures relating to our financial reporting. The actions that we are taking are subject to ongoing executive management review, and will also be subject to audit committee oversight. Although we plan to complete this process as quickly as possible, we cannot at this time estimate how long it will take, and our initiatives may not prove to be successful in addressing the material weakness. If we are unable to successfully address the material weakness, and if we are unable to produce accurate and timely financial statements, our share price may be adversely affected and we may be unable to comply with applicable stock exchange listing requirements.

JOBS Act Exemptions

On April 5, 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an emerging growth company, we are electing to take advantage of the following exemptions:

- including two years of audited financial statements as opposed to three years;
- not providing an auditor attestation report on our internal control over financial reporting; and

not providing all of the compensation disclosure that is required of non-emerging growth public companies under the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our ordinary shares held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period.

Our Company

Forward Pharma is a Danish biopharmaceutical company preparing to initiate a Phase 3 clinical trial using FP187, a proprietary formulation of dimethyl fumarate, or DMF, for the treatment of multiple sclerosis, or MS, patients. Since our founding in 2005, we have worked to advance unique formulations of DMF, an immune modulator, as a therapeutic to improve the health and well-being of patients with immune disorders including MS. FP187, our clinical candidate, is a DMF formulation in an oral dose that employs both matrix and delayed release technologies to control drug release which we plan to advance for the treatment of relapsing remitting MS, or RRMS, and other immune disorders, such as psoriasis.

Our Focus on DMF

Oral drugs employing DMF as an active pharmaceutical ingredient, or API, have been in use for over half a century. Today, DMF is the API found in Tecfidera®, which Biogen Idec Inc., or Biogen, began selling for the treatment of RRMS following approval by the U.S. Food and Drug Administration, or FDA, in March 2013 (and approval by the European Commission, or EC, in February 2014). Tecfidera®, which is an oral dose of 480 mg of DMF daily (240 mg twice daily), generated global sales from launch in April 2013 through the end of 2013 of \$876 million. DMF is also an API found in Fumaderm®, which has been sold for the treatment of psoriasis since 1994.

In 2004, a private Swedish company Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech General Partners ApS (an affiliate of one of our largest shareholders), assessed the potential for DMF to become a significant global product. Aditech specifically focused on the development of an innovative delayed and controlled release formulation of DMF, with the goal of limiting side effects typically associated with DMF treatment.

We were founded in 2005 for the purpose of exploiting a patent family Aditech filed relating to, among other things, its delayed and controlled release formulation for DMF, and in 2010 we acquired this patent family from Aditech. Under our agreements with Aditech, we obtained, among other things, Aditech's patents and associated know-how related to DMF formulations. See "Related Party Transactions – Aditech Agreement."

The patent family that we acquired from Aditech included an international patent application filed in 2005, disclosing, among other things, formulations of DMF that provide for its controlled release in the small intestine, where we believe that DMF has its immunomodulatory impact. This international application became the basis for a family of national patent applications which subsequently were filed relating to DMF. Two European patents, one from the original Aditech patent family and one from a patent family of ours (involving erosion matrix formulations of DMF with a thin enteric coating) have been granted and both are now the subject of opposition proceedings. In the U.S., two of our patent applications have been found allowable. One of those applications claims particular up-titration schedules of using DMF to treat MS, while the other claims to treat MS using particular compositions containing DMF and that also specify levels of a DMF metabolite called mono methyl fumarate, or MMF, in the bloodstream. In a third application, the Examiner has found our claims directed to methods of treating MS using a 480 mg dose of DMF to be allowable and has recommended that an interference be declared against Biogen's U.S. Patent No. 8,399,514.

In order to assess FP187's safety profile for human use, we have performed 28 pre-clinical studies on DMF since 2006, gathering data through animal testing (and in certain cases *in vitro* testing of DMF in cells) on its pharmacological activity, toxicity profile, and on dosing level effects. Beginning in 2007, we commenced a set of Phase 1 clinical trials followed by a Phase 2 clinical trial to investigate, among other things, safety and dosing tolerability of FP187. We have successfully completed all of these clinical studies, collectively involving over 300 psoriasis patients and healthy volunteers, and gathering substantial positive safety and dosing data.

To advance FP187 for use as a drug to treat RRMS in the U.S., in August 2013 we held a pre-Investigational New Drug, or IND, Application meeting with the FDA. Prior to this pre-IND meeting, we submitted a briefing book to the FDA, which included our high-level description of a proposed 48-week Phase 3 trial, which we expect will include up to 2,000 subjects. The primary and key secondary efficacy endpoints, respectively, for the proposed Phase 3 trial will be annual relapse rate, or ARR, and a favorable change in the sustained accumulation of disability, or SAD, in each case for RRMS patients. Our pre-IND meeting submission noted that we intend to compare FP187 to an active beta interferon, or IFN β , comparator drug. We expect to file our IND for RRMS by the end of April 2014 and to submit the protocol for our Phase 3 study in the third quarter of 2014.

Following completion of our planned Phase 3 trial, we intend to submit to the FDA our New Drug Application, or NDA, for FP187 to treat RRMS. Approval by the FDA of an NDA is dependent on a number of factors. A final decision as to whether the program we shared with the FDA in advance of our pre-IND meeting is sufficient to support approval (including the sufficiency of our proposed single Phase 3 trial and whether a favorable change in SAD will need to be demonstrated by us at the time of our NDA submission) can only be made by the FDA once it has reviewed our full NDA, including the data from our Phase 3 study. We expect that patient enrollment for the Phase 3 trial we are contemplating will take at least 18 months, with completion of the final patient's initial 48-week treatment period after a total of 30 months. When the last patient dosed has completed the 48-week treatment period, we expect that we will have a substantial number of patients with two years of data, which we believe will allow us to complete an analysis of the effects of FP187 on SAD which can be provided to the FDA when we submit our NDA. As a result, we believe that any requirement by the FDA for data on SAD will not delay a decision on whether to approve FP187 for the treatment of RRMS.

We intend to submit our NDA for FP187 to treat RRMS under Section 505(b)(1) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDC Act, based on pre-clinical and clinical data we have and will have developed and independently own. Section 505(b)(1) of the FDC Act prescribes how a product may be submitted for approval by the FDA as a new drug based on clinical trial data and other information independently developed and owned by the party making the NDA submission, or obtained from a third-party with a right of reference.

In Europe, we have held preliminary discussions concerning marketing authorization for FP187 with the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, or BfArM) in Germany, and more recently in November 2013 held a scientific consultation with the European Medicines Agency, or EMA. We expect to apply for a European Union, or EU, marketing authorization for FP187 to treat RRMS.

We also intend to pursue the development of FP187 for the treatment of psoriasis, and expect to commence a Phase 3 clinical trial program for psoriasis beginning in 2014.

History of DMF

A German pharmacist discovered in the late 1950s that fumaric acid derivatives were useful for the treatment of psoriasis. Over the following years, various blends of fumaric acid derivatives, including DMF, were tested and used in different doses throughout Germany and, later, in other parts of Europe. Pharmacies in Germany often made their own compounded versions for the treatment of psoriasis.

In 1994, Fumapharm AG (acquired by Biogen in 2006) received approval in Germany to market Fumaderm®, which contains DMF and three ethyl fumaric ester salts, for the treatment of psoriasis. DMF is also the sole API in Biogen's Tecfidera®. Fumaderm® has not been approved outside of Germany, but it is nonetheless available throughout Europe as a prescription drug sourced from German pharmacies. Tecfidera® is sold in both the U.S. and Europe. We estimate that there have been well over 150,000 patient years of exposure to drugs containing DMF.

Our Intellectual Property

We divide our intellectual property portfolios primarily into two basic patent families, which we refer to as our "Core Composition Patent" family and our "Erosion Matrix Patent" family. Our Core Composition Patent family, based on international application PCT/DK2005/000648, filed by Aditech in 2005, discloses a broad range of controlled release pharmaceutical compositions of DMF as well as the use of a dose of about 480 mg of DMF per day to treat MS. Our Erosion Matrix Patent family, based on international application PCT/EP2010/050172, filed in 2010, discloses our delayed and controlled release formulations of DMF in FP187.

Core Composition Patent family

In the EU, a patent from our Core Composition Patent family, EP2316430, has been granted. EP2316430 covers DMF formulations with certain in vitro dissolution profiles. In the U.S., U.S. Application Nos. 13/957,117 and 13/957,220 have been allowed.

U.S. Application No. 13/957,117 claims the use of delayed release formulations of DMF to treat MS according to an up-titration schedule that reaches a total daily dose of about 480 mg. U.S. Application No. 13/957,220 claims a method of treating an MS subject with about 480 mg of DMF per day, using delayed release formulations containing from about 120 mg to 240 mg of DMF which, following administration, result in certain levels of MMF in the bloodstream.

Two third-party pre-issuance submissions have recently been filed with the USPTO, questioning the patentability of the claims in each of the two U.S. patent applications from our Core Composition Patent family that have been allowed. We have filed a response to the third-party pre-issuance submission in Application No. 13/957,117 and are prepared to do so in Application No. 13/957,220. We believe the third-party submissions are defective and, even if they are considered by the USPTO, expect both of our patent applications to be issued as patents.

We were recently informed by the USPTO Examiner that she believes the claims in another of our patent applications in the Core Composition Patent family, U.S. Application No. 11/576,871, to be allowable and in consultation with her supervisor and a patent interference specialist, has recommended both that an interference be declared against Biogen's U.S. Patent No. 8,399,514, whose claims also cover a method of treating MS using about a 480 mg daily dose of DMF, and that we be designated as the so-called senior party.

The USPTO website indicates that the Examiner has prepared a memorandum in support of an interference, which will be reviewed by an administrative patent judge. Such interference, if declared, will give us the opportunity to prove to the USPTO that we were the first to invent the method of treating MS using about a 480 mg daily dose of DMF.

Multiple third parties, including Biogen, are opposing our patent EP2316430 (covering DMF formulations) before the European Patent Office, or EPO. In view of the publication of WO2006/037342, the international application in the Core Composition Patent Family, on April 13, 2006, prior to Biogen's February 8, 2007 filing on the use of the 480 mg daily dose to treat MS, we (along with multiple other parties) have filed an opposition against Biogen's EP2137537 B1 patent which has claims that cover this dosing regimen.

Erosion Matrix Patent family

In the EU, a patent from our Erosion Matrix Patent family, EP2379063 (covering matrix formulations with a thin enteric coating), has been granted. Multiple third parties, including Biogen, are opposing this patent before the EPO. The U.S. counterpart, U.S. Application No. 13/143,498, was allowed by the USPTO but withdrawn from allowance to permit the USPTO Examiner to consider the opposition papers in EP2379063.

Other patent families

Beyond our Core Composition Patent and Erosion Matrix Patent families, our other patent families include pending applications in the EU and the U.S., mainly directed to new dosing regimens of DMF. We believe that our overall patent portfolio, when mature, will position FP187 competitively in the key markets of the U.S. and the EU.

Our Business Strategy

We have focused on DMF's potential as an immune-modulating drug to improve the health and well-being of patients with immune disorders for approximately the past 10 years, during which time we have assembled and continue to develop our intellectual property portfolio and regulatory strategy. We believe our intellectual property portfolio, combined with the clinical data we have and will have independently obtained and the discussions we have had with the FDA, BfArM and EMA, provide us with the opportunity to pursue the development of FP187 for the treatment of RRMS in the U.S. and the EU. We intend to use the net proceeds from this offering to, among other things, pursue a Phase 3 clinical trial of FP187 for the treatment of RRMS which we believe, if successful, would (in combination with other data on FP187 we have and are obtaining) allow us to submit an NDA in the U.S. and a separate marketing authorization application in the EU for FP187 to treat RRMS. We intend to also pursue the development of FP187 for the treatment of psoriasis, including commencing a Phase 3 clinical trial program beginning in 2014.

Components of our business strategy include:

- **Successfully develop FP187 for the treatment of Relapsing Remitting Multiple Sclerosis.** We plan to pursue approval from the FDA and the EC of FP187 for the treatment of RRMS. We believe that, if approved, FP187 could become an important therapeutic in the multi-billion dollar MS drug market.
- **Develop FP187 for the treatment of psoriasis.** We plan to pursue FP187 for the treatment of psoriasis. We believe that, if approved, FP187 could become a compelling treatment option for patients with psoriasis.
- **Exploit and defend our intellectual property rights.** We believe our patents and patent applications related to, among other things, our proprietary formulation technology, combined with our patents and patent applications claiming dosing levels of DMF, are critical assets of our company. We intend to exploit our intellectual property by continuing to pursue our patent applications, and to defend our patent rights as we deem necessary for our business.
- **Obtain marketing exclusivity in the U.S. and the EU for FP187.** In addition to patent protection, if and when an NDA is approved, we will be entitled to up to three and one-half years of marketing exclusivity against generic versions of FP187 in the U.S. In the EU, we will be entitled to up to 11 years of exclusivity from the first date of authorization in the EU.
- **Potentially partner FP187 with third parties.** We may opportunistically seek commercial partners for FP187 to offset risk and preserve capital, if appropriate, although we intend to retain key development and commercialization rights. We believe retaining this strategic flexibility will help us to maximize shareholder value.
- **Continue to explore, and potentially develop, FP187 and other DMF-related formulations for the treatment of other immune disorders.** We intend to continue to explore and potentially develop FP187 and other DMF-related formulations for the treatment of other immune disorder indications, if we determine that such development could be commercially viable.

Mode of Action of DMF and our Proprietary Formulation

Mode of action

While the exact mode of action of DMF is not fully understood, we believe that some of its therapeutic effects are mediated via modulation of the immune system. From studying immune cells in vitro we believe that DMF can rapidly form adducts by combining with the antioxidant molecule glutathione, or GSH, leading to the functional depletion of GSH, followed by the modulation of various cellular pathways. We believe that one important downstream event of intracellular GSH depletion is the increased expression of the anti-inflammatory stress protein HO-1, with subsequent induction of type II dendritic cells leading to a reduction of inflammatory responses. We also believe that the depletion of GSH can induce apoptosis or cell death in different cell types including activated T cells, reducing inflammatory responses. Other pre-clinical data, we believe, have indicated that DMF can also protect cells, including neuronal cells, against oxidative stress.

In animal models, GSH/DMF adducts have been found in the gastrointestinal mucosa and in the portal vein blood, but not in organs like the heart, brain and liver, which suggests to us that the clinical effects of DMF may be mediated at least in part by DMF exerting its action within the tissues in the intestine or pre-systemic circulation. Such a mode of action of DMF is also supported, we believe, by the fact that DMF has not been directly detected in the bloodstream.

Some proportion of DMF is thought by us to be metabolized by esterases (enzymes ubiquitous in the gastrointestinal, or GI, tract) to produce MMF. In contrast to DMF, MMF can be measured in the bloodstream, but the extent to which it may contribute to clinical efficacy is currently unclear to us. However, recent pre-clinical research suggests to us that sudden plasma peaks of MMF may contribute to the side effect of flushing via interaction with nicotinic acid receptors.

Formulation and clinical profile of FP187

Our proprietary DMF formulation, FP187, employs two strategies which we believe improve the release of DMF by reducing the peaks of MMF in the bloodstream while maintaining overall DMF exposure levels, which, in turn, may control DMF's side effects. FP187 uses an enteric coating material, which forms a polymeric barrier around each DMF-containing core tablet for the purpose of inhibiting the release of DMF in the stomach and allowing for release in the small intestine. In addition, the DMF in FP187 is formulated as an erosion matrix, resulting in what we believe to be a controlled release of DMF in the small intestine after the enteric coating has dissolved. The enteric coating employed by FP187 is thinner than the coating used by the other DMF products, which we believe results in earlier release of DMF in the small intestine.

We think that products containing DMF that lack an erosion matrix formulation (such as Tecfidera® and Fumaderm®) may result in DMF being released in a more concentrated and immediate burst. We believe that the slow rate of release of DMF permitted by FP187's erosion matrix formulation greatly reduces, or even eliminates, the peaks of MMF in the bloodstream observed with formulations in which the DMF is not incorporated into a controlled release matrix, while ensuring that a therapeutically effective dose of DMF is administered, potentially producing fewer and less severe flushing episodes. In addition, we believe that the controlled release of DMF from the erosion matrix formulation, together with the earlier start of release in the small intestine, may allow absorption of DMF over a larger area of GI mucosa, potentially leading to lower local GI concentrations and therefore, we believe, less GI specific side effects.

Overview of MS

MS is a chronic disorder of the central nervous system, or CNS, involving brain, spinal cord and optic nerves, and is characterized clinically by recurring episodes of neurological dysfunction. MS is immune-mediated, driven by autoreactive lymphocytes that attack the covering surrounding nerve cells, or myelin sheath. This autoimmune response results in destruction of the myelin sheath, termed demyelination, and nerve damage. The CNS destruction caused by autoreactive lymphocytes can lead to debilitating clinical symptoms such as numbness, difficulty walking, visual loss, loss of coordination and muscle weakness.

The majority of patients are diagnosed with MS between the ages of 20 and 40, with a peak at age 29 to 30. At onset, approximately 85% of such patients have what is referred to as relapsing remitting multiple sclerosis, or RRMS, characterized by recurrent acute exacerbations of neurological dysfunction followed by variable degrees of recovery with clinical stability between relapses. Almost half of such relapses result in incomplete recovery of neurological function and leave permanent disability and impairment that accumulates over time. Owing to the complications of chronic disability, life span for patients with MS is typically shortened by approximately ten years.

The early onset and progressive nature of RRMS highlights the need for treatment options that are effective, convenient and tolerable. This unmet need is particularly important for sufferers in the workforce or those raising families. The inevitability of both relapse and disease progression also results in the prescription of the newest medications that offer increased levels of efficacy and differing risk/benefit profiles. As new efficacious and safe treatments are approved, RRMS patients will have more options for treatment in earlier stages of the disease.

Clinical Development Summary

Our clinical development strategy has been designed with a view towards satisfying marketing approval requirements in both the United States and the EU, while allowing us to create an electronic common technical document that we can use for marketing authorization applications in other jurisdictions. We have conducted an extensive pre-clinical program and have completed several Phase 1 and Phase 2 clinical trials. We further plan to conduct additional Phase 1 clinical trials and a Phase 2 clinical trial in psoriatic arthritis, and are in the process of planning Phase 3 clinical trials of FP187 in RRMS and in psoriasis. Our planned Phase 3 clinical trial of FP187 in RRMS is particularly large, with up to 2,000 patients to be enrolled.

Completed clinical trials

The following table sets forth information regarding completed clinical trials involving FP187:

Study	Phase	Total Patients Enrolled	Trial Design	Status	Dates
FP187-101	Phase 1	24	Randomized, single dose (240 mg) three way crossover PK study in healthy volunteers	Completed	January 15, 2007 – April 28, 2008
FP187-102	Phase 1	20	Randomized, single dose (240 mg) four way crossover PK study in healthy volunteers	Completed	November 11, 2008 – April 17, 2009
FP187-103	Phase 1	18	Randomized, single dose (240 mg) three way crossover PK study in healthy volunteers	Completed	February 4, 2009 – July 28, 2009
FP187-201	Phase 2 (Psoriasis)	252	Randomized, double-blind, placebo controlled, 20 week treatment period study with three FP187 dose groups with two dosage levels and an open, flexible up-titration group.	Completed	September 7, 2010 – January 9, 2012

Our extensive pre-clinical data, combined with our positive Phase 1 and 2 clinical trial results, has enabled us to now consider developing DMF for RRMS, psoriasis and potentially other immune disorders.

Pre-clinical studies

To assess FP187's safety profile for human use, we have performed 28 pre-clinical studies on DMF since 2006, gathering data on its pharmacological activity, toxicity profile, and on dosing level effects through animal testing and *in vitro* testing of DMF in cells. This pre-clinical program included, among other tests, seven safety pharmacology studies, three single and multiple dose toxicokinetic studies, four studies on metabolism and drug interaction, two distribution studies, four acute toxicity studies, three dose-range repeat studies, two 28 day repeat dose toxicity studies, two 13 week repeat dose toxicity studies, and a four-part genotoxicity study.

In Europe, the EMA and BfArM do not require further pre-clinical testing other than short-term reproductive toxicology studies that we plan to perform. No additional long-term toxicology or carcinogenicity studies will be required for our marketing authorization application in Europe.

In the U.S., carcinogenicity studies will be required and such studies are included in our development plan. We have recently received recommendations on our plans to perform pre-clinical carcinogenicity studies on DMF from the FDA's Executive Carcinogenicity Assessment Committee, or CAC, and we have taken these recommendations into account in the design of our planned studies.

Initial Phase 1 and 2 clinical trials

In 2007, we commenced our clinical trial program in Germany in coordination with BfArM. We conducted a set of Phase 1 clinical trials, followed by a Phase 2 clinical trial. These trials included over 300 subjects consisting of psoriasis patients and healthy volunteers, and investigated, among other things, safety and dosing tolerability of FP187. We have successfully completed all of these clinical trials, gathering substantial positive safety and dosing data.

Phase 1 trials

We conducted three Phase 1 clinical trials of FP187, which tested seven delayed and controlled release formulations and dosing regimens of DMF. In two of these clinical trials, we compared a 240 mg dose of FP187 with Fumaderm®, which includes 240 mg of DMF in an enteric-coated tablet. Since DMF is not quantifiable in the bloodstream after oral administration, we measured level of MMF, the main metabolite of DMF. The primary objectives of these trials were:

- the determination of the pharmacokinetic, or PK, properties of MMF, with a secondary objective of the evaluation of safety and tolerability (FP187-101 involving 24 healthy male volunteers);
- the determination of the PK properties of MMF, with secondary objectives of comparing bioavailability of the formulations with Fumaderm® and evaluating the safety and tolerability of FP187 (FP187-102 involving 20 healthy male volunteers); and
- the determination of PK properties of MMF with secondary objectives of comparing bioavailability of the formulations with Fumaderm® and to evaluate the safety and tolerability of FP-187 (FP187-103 involving 18 healthy male volunteers).

Phase 2 trial

After completion of our Phase 1 trials, we continued the clinical development of FP187 with a randomized, placebo-controlled, double-blind, parallel-group Phase 2 trial in patients with psoriasis (FP187-201, clinicaltrials.gov identifier: NCT01230138). The trial was conducted in 17 centers in Germany.

Trial design

The primary endpoint was to analyze the effect of FP187 daily doses of 500 mg (given as 250 mg twice daily, or BID) and 750 mg (given as 375 mg BID or 250 mg thrice daily, or TID) and of placebo on the proportion of patients achieving a PASI75 response (reduction in Psoriasis Area and Severity Index, or PASI, of at least 75% from baseline) after 20 weeks of treatment.

Secondary endpoints were to evaluate the efficacy and safety as assessed by PASI, static Physician's Global Assessment, or sPGA, patient global assessment, or PaGA, patients' disease-related quality of life score, patient assessed pruritus, Adverse Events, or AE, and Serious Adverse Events, or SAEs.

Included were male and female patients at least 18 years of age, with a clinical diagnosis of psoriasis with a body surface area of no less than 10% and at least a PASI of 10, and with stable disease for at least 6 months prior to study start. Exclusion criteria included prior discontinuation of treatment with other DMF containing products.

The trial design included an up-titration schedule of two weeks to the 500 mg dose and three weeks to the 750 mg dose. A separate open-label flexible up-titration treatment arm (target dose 750 mg) was added to the study to investigate impact on tolerability of a more flexible and longer up-titration period.

Statistical analysis

The primary efficacy analysis was performed based on the full analysis (FA) set (randomized patients receiving at least one dose of trial drug) and the per protocol (PP) set (patients of the FA set without major protocol violations and a PASI evaluated at week 8 or later). For the primary endpoint to be met, both the PP and FA analysis sets individually needed to be significant, and the two 750 mg dose groups were pooled, as per the prospectively defined analysis strategy.

Patient disposition

In the blinded patient arms, 199 patients were randomized. Out of these, 192 patients received study medication at least once, and 92 patients discontinued prematurely. The discontinuation rate was higher in the placebo group (56%) than in the active treatment groups (40% and 48% for 500 mg and pooled 750 mg, respectively).

Efficacy

The primary endpoint was met for the 500 mg dose group at week 20 and was statistically significantly higher compared to placebo in both the FA set (PASI75 responder rate 31.3% vs. 10.4%; $p=0.01$) and the PP set (PASI75 responder rate 45.5% vs. 13.5%; $p<0.01$).

For the pooled 750 mg dose group, the responder rate at week 20 was statistically significantly higher compared to placebo for the PP set (PASI75 responder rate 35.1% vs. 13.5%; $p=0.01$) but not for the FA set (PASI75 responder rate 20.8% vs. 10.4%; $p=0.12$).

The efficacy results from the blinded study were supported by those of the open flexible up-titration arm, with PASI75 responder rates for FP187 vs. placebo of 41.5% vs. 10.4% in the FA population ($p<0.01$) and of 57.9% vs. 13.5% in the PP population ($p<0.01$).

Safety

Seven SAE's were reported in the FP187 treatment groups, of which two were considered possibly related to the study drug. No deaths were reported in the trial. No notable difference between active and placebo arms was seen for the frequency of infections, change in pulse, blood pressure or weight, change in triglycerides, cholesterol, HDL-C or LDL-C, change in liver enzymes, creatinine, or creatinine clearance (Cockcroft-Gault-Formula). A mild eosinophilia was observed in all treatment groups, including the placebo group, whereas moderate and severe eosinophilia occurred only in FP187 treatment groups. Similarly, a mild lymphopenia was observed in all treatment groups, including the placebo group, whereas moderate and severe lymphopenia occurred only in FP187 treatment groups. Most returned to pre-treatment values during the course of the study or were considered by the investigator to be not clinically relevant at the end of the study. Both eosinophilia and lymphopenia are well documented AEs of fumaric acid ester therapy. No increased rate of infection among patients with lymphopenia was seen.

Tolerability

Gastro-intestinal, or GI, AE and flushing are well-known side effects for fumaric acid ester treatment.

While the majority of patients treated with FP187 reported at least one GI tolerability event, such as diarrhea or abdominal pain, the median number of GI events per patient in the 500 mg and 750 mg groups was only two, and 92% of events were mild or moderate. Flushing was reported by 4%, 17% and 13%, for the placebo, 500 mg, and 750 mg groups, respectively. The median number of flushing events per patient in the 500 mg and 750 mg groups was 1, and 100% of events were mild or moderate. GI-related events and flushing mainly occurred within the first four weeks of the study, as has been reported for other fumaric acid ester therapies. The overall discontinuation rate in our trial was lower in all active therapy arms than in the placebo arm. Flushing events appeared to be recorded at a lower rate in the 500 mg and 750 mg doses of FP187 than the rate seen in most clinical trials with DMF-containing products, but this has not been confirmed by a head-to-head study.

Planned clinical trials and market authorization application strategy

To advance FP187 for use as a drug to treat RRMS in the U.S., we held a pre-Investigational New Drug, or IND, application meeting with the FDA in August 2013. Prior to this pre-IND meeting, we submitted a briefing book to the FDA, which included our high-level description of a proposed 48-week Phase 3 trial, which we expect will include up to 2,000 RRMS patients. The primary and key secondary efficacy endpoints, respectively, for the Phase 3 trial will be ARR and a favorable change in the sustained accumulation of disability, or SAD, in each case for RRMS patients. Our pre-IND meeting submission noted that we intend to compare FP187 to an active beta interferon, or IFN β , drug. We expect to file our IND for RRMS in April 2014 and to submit the protocol for our Phase 3 study by August 2014.

Following completion of our planned Phase 3 trial, we intend to submit our NDA for FP187 to treat RRMS. Approval by the FDA of a New Drug Application, or NDA, is dependent on a number of factors. A final decision as to whether the program we shared with the FDA in advance of our pre-IND meeting is sufficient for approval (including the sufficiency of our proposed single Phase 3 trial and whether a favorable change in SAD will need to be demonstrated by us at the time of our NDA submission) can only be made by the FDA once it has reviewed our full NDA package, including the data from our Phase 3 study. We will also be required to provide information in our NDA on adequate dose exploration of FP187 in patients with MS.

We intend to submit the same pre-clinical and clinical data package to the EMA following our RRMS NDA submission to the FDA.

We also intend to pursue the development of FP187 for the treatment of psoriasis, and expect to commence a Phase 3 clinical trial program for psoriasis beginning in 2014.

Phase 1 and Phase 2 trial(s)

We intend to conduct the following additional Phase 1 trials to further investigate the safety profile of FP187 for human use:

- PK fasting/fed trial: This will be a 3-way randomized cross over trial investigating the effect of food on the pharmacokinetics of MMF. The study will include 21 healthy volunteers (males and females) and include kinetic blood sampling over 12 hours after each administration of FP187 (250 mg as a single dose), or the comparator (Tecfidera® 240 mg as a single dose) with standard laboratory evaluations and AE and tolerability reporting.
- QT/QTc study: This is a standard study to be carried out for FP187 and overseen by a specialized clinical research organization.
- We may be required to conduct bridging studies in order to reference data from previous pharmacokinetic investigations. These will be standard Phase 1 trials.

In addition, a human mass-balance/metabolic profile study and an alcohol dumping study may need to be performed.

We are in advanced planning for a proof of concept Phase 2 clinical trial of FP187 in psoriatic arthritis. This clinical trial, if it is conducted, would be a randomized, double-blind and placebo controlled trial, with 30 patients initially, in a 1:1 randomization. The primary endpoint would be the proportion of patients with an improvement of ACR 20 (American College of Rheumatology 20% improvement response criteria) and a secondary set of endpoints evaluating ACR 50 and ACR 70, as well as LEI (Leeds enthesitis index) and standard safety and tolerability. The planned treatment dose is 500 mg/day (250 mg BID) and the planned treatment time is 24 weeks. Patients who respond to ACR 20 will be offered an opportunity to continue on an open-label 500 mg daily dose, and be followed for an additional 28 weeks to obtain long term efficacy and safety results. There will be an initial tolerability testing period and patients who do not tolerate the DMF treatment after four weeks will be excluded from the trial.

Phase 3 trials

Phase 3 clinical trial of FP187 in RRMS

We currently intend to conduct a single double-blind, double-dummy 48-week active comparator Phase 3 trial of FP187 in RRMS. We intend to compare two dosing levels of FP187 (400 mg daily (200 mg BID), and 480 mg daily (240 mg BID)) to an IFN β RRMS drug. The 480 mg/day dose is the labeled DMF dose for Tecfidera®, and the lower dose is being tested to explore its safety and efficacy.

The primary efficacy endpoint of this trial will be ARR at week 48. The secondary endpoints consist of: new and total Gadolinium-enhanced, or GdE, lesions on magnetic resource imaging, or MRI, scans at week 24, 36 and 48; new or enlarging T2-hyperintensive lesions at week 24, 36 and 48; new T1-hyperintense lesions at week 24, 36, and 48; proportion of relapse-free patients at week 48; brain volume at week 48; and proportion of patients with confirmed progression of Expanded Disability Status Score, or EDSS, a measure of SAD (a key secondary endpoint). While the primary efficacy data will be based on 48-week data, patients will continue treatment for 96 weeks, after which patients can continue on FP187 until the product is available for commercial use.

We plan to design this trial to detect a 30% reduction in ARR compared to the IFN β comparator drug with 90% power, which we estimate will require up to approximately 600 patients in each of the two FP187 dosing regimen arms and up to approximately 800 patients in the comparator drug arm; a combined total of up to 2,000 patients. We intend to design the trial to include an interim look at the data to assess, among other things, futility, sample size and probability of achieving a two-sided p-value of less than 0.01. We expect patient recruitment to take up to 18 months, with the last patient completing his or her 48-week study period approximately 30 months after the first patient is enrolled.

The safety and tolerability assessment will be based on full laboratory evaluation at every visit, and detailed collection of AE information including GI, flushing and infection AEs.

Phase 3 clinical trial of FP187 in psoriasis

We are continuing advanced preparatory work for an active comparator and placebo controlled confirmative non-inferiority Phase 3 trial of FP187 for the treatment of psoriasis in Europe, which we expect to include approximately 650 psoriasis patients, as well as an additional placebo controlled Phase 3 trial of FP187 for the treatment of psoriasis in the United States, which we expect to include approximately 700 psoriasis patients. We anticipate that, in 2014, the first patient dosing in the European Phase 3 trial will occur and we will continue preparation for the U.S. Phase 3 clinical trial. We believe that Phase 3 trials of FP187 for the treatment of psoriasis could provide important long-term (3 – 4 year) safety data concerning the use of FP187 in a large population at doses similar to those we plan to test for use in RRMS.

The European Phase 3 trial is planned for five countries with a total of approximately 60 sites, of which approximately 23 sites are in Russia and the Ukraine. If political instability in Russia and the Ukraine worsens or if sanctions are implemented, our ability to proceed or continue with sites in these countries could be adversely impacted. See “Risk Factors – Risks Related to the Development, Clinical Testing, Regulatory Approval and Commercialization of FP187 – Instability in Russia and the CIS could adversely affect our planned Phase 3 clinical trials for FP187 for the treatment of psoriasis.”

Exclusivity

Exclusivity in the U.S

We intend to submit our NDA for FP187 to treat RRMS under Section 505(b)(1) of the FDC Act, based on pre-clinical and clinical data we have and will have developed and independently own. Approval of an NDA submitted under Section 505(b)(1) of the FDC Act for a single active ingredient product that does not include a new chemical entity, but which contains reports of new clinical investigations that were essential for approval, should entitle us to three years of marketing exclusivity against generic versions of FP187, with the potential to extend the exclusivity by six months if we perform a pediatric clinical trial that meets the study requirements provided for in an FDA-issued written request. If we perform additional clinical trials essential for approval of other indications, we could also obtain three years of marketing exclusivity for those new indications.

European approach and exclusivity

We have discussed our European regulatory strategy for the approval of FP187 for the treatment of subjects with RRMS with the BfArM in Germany and more recently in a scientific consultation we had in November 2013 with the European Medicines Agency, or EMA. We expect to apply for an EU-wide marketing authorization to be granted by the European Commission under the so-called “centralized” procedure (Regulation EC 726/2004). See “Government Regulation – European Union – Marketing authorization applicable and available authorization procedures.” We plan to be able to file a full clinical package, on the basis of our planned Phase 3 clinical trial, our planned/completed pre-clinical studies, and materials to be prepared for the NDA submission in the U.S.

For a psoriasis indication, we may use a “full-mixed” application in Europe, allowing use of bibliographical references that include, among other things, references pertaining to public clinical and pre-clinical trial papers and the clinical use of Fumaderm® in Germany and other European countries.

In Europe, the marketing authorizations we receive for the RRMS indication will entitle us to receive eight years of data exclusivity and an additional two years of marketing exclusivity from FP187’s first date of authorization in the EU for RRMS. For more, see “Government Regulation – European Union – Regulatory data protection”. Should we advance a further indication for FP187 (for example, as we are planning to do with psoriasis), one more year could be added to the exclusivity period, leading to a total market exclusivity of 11 years from the first date of authorization.

Intellectual Property Summary

We seek to protect the intellectual property and proprietary technology that we believe is important to our business, including pursuing and maintaining patents intended to cover FP187, and any other inventions that are commercially important to the development of our business.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, to exploit and defend our patents, to preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. For more information, please see “Risk Factors – Risks Related to Our Intellectual Property and Information Technology.”

As of the date of this Prospectus, we owned 18 U.S. utility patent applications, and two U.S. provisional patent applications relating to our DMF program.

We divide our intellectual property portfolios primarily into two basic patent families, which we refer to as our “Core Composition Patent” family and our “Erosion Matrix Patent” family. The following table highlights key aspects of the current status of our Core Composition and Erosion Matrix Patent families:

Patent / Application	Patent Family	Status
EP2316430	Core Composition	Granted in Europe. Subject of EPO opposition by Biogen and others
U.S. App. 13/957,117	Core Composition	USPTO indicates is allowed in the U.S. Third-party pre-issuance submission filed
U.S. App. 13/957,220	Core Composition	USPTO indicates will be allowed in the U.S. Third-party pre-issuance submission filed
U.S. App. 11/576,871	Core Composition	Interference recommended by Patent Examiner. Decision by the USPTO Administrative Law Judge to proceed with interference is pending
EP2379063	Erosion Matrix	Granted in Europe. Subject of EPO opposition by Biogen and others
U.S. App. 13/143,498	Erosion Matrix	Allowed in the U.S. Request for continued examination to be filed to permit the USPTO Examiner to consider the opposition papers in EP2379063

As we have described above, Biogen has patents and is also prosecuting a number of additional patent families that could adversely impact our commercial efforts if our marketing of FP187 for treatment of RRMS were ultimately found to infringe any valid claim. Two of Biogen's patent families, the first in the U.S. concerning the use of an amount of a pharmaceutical preparation of DMF effective for treating MS, and the second in both Europe and the U.S. claiming the use of a dose of about 480 mg of DMF per day to treat MS, are the patents most likely to impact our business adversely if Biogen were to successfully show that our activities infringe any valid claim. This is particularly true if Biogen obtains patent term extensions for certain key patents in the U.S. and/or Supplemental Protection Certificates (which also extend the effective life of patents for drugs) in Europe. As referenced in the "Risk Factors" section of this Prospectus, while there can be no assurances we would prevail against Biogen in any infringement suit, we believe that a combination of underlying weaknesses with these patent families and the earlier priority date of our own patent claiming the use of a dose of about 480 mg of DMF per day to treat MS will enable us to successfully implement our business plan.

We have analyzed the use of DMF to treat immune-modulated disorders, including RRMS, and we have concluded in good faith that our business plan will not lead us to infringe any valid claim of Biogen's intellectual property rights. As our formulation of DMF is proprietary, and the regulatory pathway we have planned for FP187 should not require that we refer to findings made by the FDA with regard to Biogen's NDA or marketing authorizations, we do not expect that regulatory exclusivity granted to Biogen for approval of DMF as a new chemical entity will negatively affect the implementation of our business plan.

Any patents issued from patent applications based on PCT/DK2005/00648 will expire on October 7, 2025, subject to patent term adjustments in the U.S. Any patents issued from patent applications based on PCT/EP2010/050172 will expire on January 8, 2030, subject to patent term adjustments in the U.S.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent. The patent term of a European patent is 20 years from its filing date, which, unlike in the U.S., is not subject to adjustment.

Other Opportunities for FP187

We have explored performing clinical studies in other indication areas, including psoriatic arthritis (an immune disorder characterized by inflammation of the joints alone or in both skin and joints which occurs in about 15% of psoriasis patients) and other immune mediated diseases, including for many disease indication that we believe would entitle us to submit for Orphan Drug status.

Manufacturing

FP187 is a small 8 x 5 mm tablet that contains DMF in an erosion matrix; each erosion matrix tablet core is covered by a thin enteric coating.

Currently, a single manufacturer provides us with our DMF, which is our API for FP187. Production procedures and facilities operated by this manufacturer have been validated for the current batch size in 2013, and we are planning to validate an increased batch size during 2014.

Formulation and finishing for our FP187 tablets is completed by another single manufacturer currently. Production procedures and facilities for this manufacturer have been validated by us for the current batch size, and we are planning to validate an increased batch size in 2014. Currently 16 batches have consistently been produced under GMP conditions for use in our Phase 3 trial for psoriasis.

We are actively reviewing alternative secondary suppliers of both DMF and our formulated and finished FP187 tablets.

Material Agreements

Aditech agreements

In 2004, a private Swedish company Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech Advisors (an affiliate of one of our largest shareholders), began developing and filing patents for, among other things, an innovative delayed and controlled release formulation for DMF. In 2005 we entered into a patent license agreement with Aditech to license this patent family from Aditech, and in 2010 we acquired this patent family from Aditech pursuant to a patent transfer agreement. Under our agreements with Aditech, we obtained, among other things, Aditech's patents and associated know-how related to DMF formulations and delivery systems, subject to both diligence and minimum annual expenditure (€1.0 million per year) obligations on our part (with an option for Aditech to receive back, for no consideration, all of our DMF related assets should we fail to satisfy these obligations), as well as a payment by us to Aditech of up to 2% of net sales generated from our DMF products and processes. Further, our agreement with Aditech gives Aditech a 90-day right of first offer to acquire non-DMF related intellectual property assets we might choose to sell.

Framework agreement

Our principal shareholders, Nordic Biotech K/S, Nordic Biotech Opportunity Fund K/S, or NBOF, BML Healthcare, I, L.P. and NB FP Investment K/S, or NBFPI, intend to enter into a framework agreement prior to consummation of this offering and to which we may also become a party. Among other things, each of the corporate actions described below shall occur prior to (or in connection with) the consummation of this offering:

- We shall hold an extraordinary general meeting pursuant to which our shareholders will authorize our board of directors to issue new shares without pre-emption rights for our existing shareholders, which shares shall be subscribed for at the initial public offering; and
- Prior to our board's approval of the offer price and the allocation of ordinary shares offered by this Prospectus to eligible investors, we shall hold an extraordinary general meeting at which the Share Conversion will be authorized, pursuant to which all of our outstanding Class A shares and Class B shares shall be converted into ordinary shares. The Share Conversion will be effectuated prior to consummation of this offering.

Competition

We are engaged in segments of the pharmaceutical and biotechnological industries that are highly competitive and rapidly changing. Large pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations are commercializing or pursuing the development of products that target immune disorders, including the same diseases we are targeting. If FP187 is approved for the treatment of RRMS, we expect it will face intense and increasing competition as new products enter the RRMS markets and advanced technologies become available. FP187 will face competition based on its safety and effectiveness, the timing and scope of regulatory approvals, the availability and cost of supply, marketing and sales capabilities, reimbursement coverage, price, patent position and other factors. Our competitors may succeed in developing competing products before we do, obtaining regulatory approval for products or gaining broader acceptance in the MS market we are targeting.

We believe that our key competitor in the DMF space is Biogen. Biogen's Tecfidera® was approved by the FDA for the treatment of RRMS on March 27, 2013. Tecfidera® generated global sales of \$876 million in 2013.

Other companies have also developed alternative therapeutic approaches for the treatment of RRMS. These include Novartis AG whose Gilenya® is a once daily oral dose drug to treat RRMS approved in September 2010, and Genzyme Corporation (a subsidiary of Sanofi S.A.), which developed Aubagio®, a RRMS drug approved in September 2012.

We also face competition from potential new entrants into the RRMS market. For example, Receptos Inc. has a product candidate, RPC1063, in Phase 2/3 testing which, if successfully approved and launched would be a once daily oral treatment for RRMS.

As we pursue the development of and FP187 is approved for the treatment of psoriasis, we will similarly face intense competition in the psoriasis market. This will include competition from products which have already been commercialized and have gained market acceptance, as well as from products based on new and advanced technologies.

Government Regulation

Our business is subject to extensive government regulation. Regulation by governmental authorities in the U.S., the EU and other jurisdictions is a significant factor in the development, manufacture and marketing of any drugs and in ongoing research and development activities. All of our products are subject to rigorous pre-clinical and clinical trials and other pre-marketing approval requirements by the FDA, the EMA and other regulatory authorities in the U.S., the EU and in other jurisdictions.

United States

In the U.S., the FDA regulates drugs under the FDC Act, and regulations implemented by the agency. If we fail to comply with the applicable United States requirements at any time during the product development process, including non-clinical testing, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include, but are not limited to, the FDA's refusal to allow us to proceed with clinical testing, refusal to approve pending applications, withdrawal of an approval, warning or untitled letters, adverse publicity, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Approval of drugs

The process required by the FDA before a drug may be marketed in the United States generally involves satisfactorily completing each of the following:

- pre-clinical laboratory tests, animal studies and formulation studies all performed in accordance with the FDA's Good Laboratory Practice, or GLP, and current Good Manufacturing Practice, or cGMP, regulations, as applicable;
- submission to the FDA of an investigational new drug, or IND, application for human clinical testing, which must become effective before human clinical trials involving testing on U.S. patients may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission of data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMPs;
- potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the NDA; and

FDA review and approval of the NDA before any commercial marketing, sale or shipment of the product.

Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based on the type, complexity and novelty of the product or disease.

Pre-clinical studies and Investigational New Drug application

Pre-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, application. The IND becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In that case, the IND sponsor and the FDA must resolve any outstanding FDA concerns before the clinical trials can begin. Submission of the IND may result in the FDA not allowing the trials to commence, either on the terms originally specified in the IND, or at all. If the FDA raises concerns or questions either during this initial 30 day period or at any time during the IND process, they may choose to impose a partial or complete clinical hold. This order issued by the FDA would delay either a proposed clinical study or cause suspension of an ongoing study, until all outstanding concerns have been adequately addressed and the FDA have notified the company that investigations may proceed. This could cause significant delays or difficulties in completing planned clinical studies in a timely manner.

Clinical trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted in accordance with federal regulations and under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. An independent Institutional Review Board, or IRB, must also review and approve the clinical trial before it can begin and monitor the study until it is completed. The IRB will consider, among other things, clinical trial design, patient informed consent, ethical factors, and the safety of human subjects. The FDA, the IRB or the sponsor may suspend or discontinue a clinical trial at any time or impose sanctions for various reasons, including a finding that the clinical trial is not being conducted in accordance with FDA requirements or the subjects are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practice rules, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, including the requirements for informed consent.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap. Additional studies may be required after approval.

Phase 1 clinical trials are initially conducted in a limited population to test the product for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.

Phase 2 clinical trials are generally conducted in a limited patient population to identify possible adverse effects and safety risks, determine the efficacy of the product for specific targeted indications and determine dose tolerance and optimal dosage. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more costly Phase 3 clinical trial.

Phase 3 clinical trials proceed if the Phase 2 clinical trials provide evidence that a dose range of the product is effective and has an acceptable safety profile. Phase 3 clinical trials are undertaken in large patient populations to further evaluate dosage, provide substantial evidence of clinical efficacy and further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites. A well-controlled, statistically relevant Phase 3 trial may be designed to deliver the data that the regulatory authorities will use to decide whether or not to approve a drug: such Phase 3 studies are referred to as “pivotal.” In most cases FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect.

In some cases, the FDA may approve an NDA for a product with the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA approval. Such post-approval trials are typically referred to as Phase 4 clinical trials. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase 4 clinical trial requirement. Failure to promptly conduct Phase 4 clinical trials could result in withdrawal of approval for products.

New Drug Application

The results of product development, pre-clinical testing and clinical trials are submitted to the FDA as part of an NDA, submitted under Sections 505(b)(1) or 505(b)(2) of the FDC Act. The NDA also must contain extensive manufacturing information and detailed information on the composition of the product and proposed labeling as well as payment of a user fee. The application fee currently exceeds \$2,169,000, and the manufacturer and/or sponsor under an approved new drug application are also subject to annual product and establishment user fees, currently exceeding \$104,000 per product and \$554,000 per establishment. These fees are typically increased annually. Once the submission has been accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under the most recent iteration of the Prescription Drug User Fee Act, or the PDUFA, the FDA has ten to twelve months in which to review a standard NDA and respond to the applicant, and six to eight months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The review process is often significantly extended by FDA requests for additional information or clarification. The review process and the PDUFA goal date may be extended by three months to consider certain late-submitted information, or information intended to clarify information already provided in the submission. The FDA may also refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of the advisory committee, but it generally follows such recommendations. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data or an additional pivotal Phase 3 clinical trial. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

At the conclusion of the FDA's review it will issue an action letter. If the FDA's evaluations of the NDA and the clinical and manufacturing procedures and facilities are favorable and there are no outstanding issues, the FDA will issue an approval letter. If the application is not approved, the FDA will issue a complete response letter, which will contain the conditions that must be met in order to secure final approval of the NDA, and when possible will outline recommended actions the sponsor might take to obtain approval of the application. Sponsors that receive a complete response letter may submit to the FDA information that represents a complete response to the issues identified by the FDA. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Once issued, the FDA may withdraw a drug approval if ongoing regulatory requirements are not met or if safety problems occur after the drug reaches the market. In addition, the FDA may require further testing, including Phase 4 clinical trials, and surveillance programs to monitor the effect of approved drugs which have been commercialized.

As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug.

The FDA has the power to prevent or limit further marketing of a drug based on the results of these post-marketing programs. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to a drug, including changes in indications, labeling or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require us to develop additional data or conduct additional pre-clinical studies and clinical trials. We cannot be sure that any additional approval for new indications for any product will be approved on a timely basis, if at all.

The FDA has several programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of serious or life-threatening conditions. These programs are intended to help ensure that therapies for serious conditions are available as soon as it can be concluded that the therapies benefits justify their risks. These programs include breakthrough therapy designation, fast track designation, priority review and accelerated approval.

Hatch-Waxman Act and Orange Book listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants ordinarily are not required to conduct, or submit results of, pre-clinical or clinical tests to prove the safety or effectiveness of their drug product. For drugs like FP187, which appears to act at least in part locally in the small intestine and pre-circulatory system and which has not been directly detectable in the bloodstream, a demonstration of bioequivalence in the context of an ANDA may require more extensive testing or even clinical trials to be conducted. Drugs approved via an ANDA are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the lawsuit that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on FDA's previous approval of a similar product, or published literature, in support of its application.

Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

To the extent that the Section 505(b)(2) applicant is relying on studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug, or a Section 505(b)(2) NDA that references the drug. Certain changes to a drug that require a clinical trial to support FDA approval, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which FDA cannot approve an ANDA or Section 505(b)(2) NDA for a drug that includes the change.

An ANDA or Section 505(b)(2) NDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the NCE exclusivity period.

Post-approval regulation

If regulatory approval for marketing of a product or new indication for an existing product is obtained, we will be required to comply with all regular post-approval regulatory requirements as well as any post-approval requirements that the FDA have imposed as part of the approval process.

For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

We will be required to report certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling requirements. Drug manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP regulations, which impose certain procedural and documentation requirements upon drug manufacturers. Accordingly, we and our third-party manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP regulations and other regulatory requirements. Discovery of problems with a product after approval for marketing may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Pediatric information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

Orphan drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition—generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA orphan drug designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA application user fee.

Disclosure of clinical trial information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

European Union

The process regarding approval of medicinal products in the EU follows roughly the same lines as in the United States and likewise generally involves satisfactorily completing each of the following:

- pre-clinical laboratory tests, animal studies and formulation studies all performed in accordance with the applicable EU Good Laboratory Practice regulations;
- submission to the relevant national authorities of a clinical trial application, or CTA, which must be approved before human clinical trials may begin;
- performance of adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication;
- submission to the relevant competent authorities of a marketing authorization application, or MAA, which includes the data supporting safety and efficacy as well as detailed information on the manufacture and composition of the product in clinical development and proposed labeling;
- satisfactory completion of an inspection by the relevant national authorities of the manufacturing facility or facilities, including those of third parties, at which the product is produced to assess compliance with strictly enforced cGMPs;

- potential audits of the non-clinical and clinical trial sites that generated the data in support of the MAA; and
- review and approval by the relevant competent authority of the MAA before any commercial marketing, sale or shipment of the product.

Pre-clinical studies

Pre-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animal studies, in order to assess the potential safety and efficacy of the product. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with the relevant EU regulations and requirements. The results of the pre-clinical tests, together with relevant manufacturing information and analytical data, are submitted as part of the CTA.

Clinical trial approval

Pursuant to the Clinical Trials Directive 2001/20/EC, as amended, a system for the approval of clinical trials in the EU has been implemented through national legislation of the member states. Under this system, approval must be obtained from the competent national authority of an EU member state in which a study is planned to be conducted. To this end, a CTA is submitted, which must be supported by an investigational medicinal product dossier, or IMPD, and further supporting information prescribed by the Clinical Trials Directive and other applicable guidance documents. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application in that country.

Clinical drug development is often described as consisting of four temporal phases (Phase 1-4), see for example EMA's note for guidance on general considerations for clinical trials (CPMP/ICH/291/95).

- Phase 1 (Most typical kind of study: Human Pharmacology);
- Phase 2 (Most typical kind of study: Therapeutic Exploratory);
- Phase 3 (Most typical kind of study: Therapeutic Confirmatory); and
- Phase 4 (Variety of studies: Therapeutic Use).

Studies in Phase 4 are all studies (other than routine surveillance) performed after drug approval and related to the approved indication.

The phase of development provides an inadequate basis for classification of clinical trials because one type of trial may occur in several phases. The phase concept is a description, not a set of requirements. The temporal phases do not imply a fixed order of studies since for some drugs in a development plan the typical sequence will not be appropriate or necessary.

Manufacturing of investigational products is subject to the holding of authorization and must be carried out in accordance with cGMPs.

Paediatric Investigation Plans

Regulation (EC) 1901/2006, which came into force on January 26, 2007, has as its primary purpose the improvement of the health of children without subjecting children to unnecessary trials, or delaying the authorization of medicinal products for use in adults.

The regulation established the Paediatric Committee, or PDCO, which is responsible for coordinating the EMA's activities regarding medicines for children. The PDCO's main role is to determine all the studies that applicants need to do in the pediatric population as part of the so-called Paediatric Investigation Plans, or PIPs.

All applications for marketing authorization for new medicines that were not authorized in the EU before January 26, 2007 have to include the results of studies carried out in children of different ages. As indicated, the PDCO determines what these studies entail and describes them in a PIP. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The PDCO can grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults, and can also grant waivers when development of a medicine in children is not needed or appropriate, such as for diseases that only affect the elderly population.

Regulation (EC) 1901/2006, which is also available in the EU, also provides for several incentives the development of medicines for children:

- medicines that have been authorized across the EU with the results of PIP studies included in the product information are eligible for an extension of their patent protection by six months. This is the case even when the studies' results are negative;
- scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of medicines for children; and
- medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate, can apply for a paediatric use marketing authorization, or PUMA. If a PUMA is granted, the product will benefit from 10 years of market protection as an incentive.

Marketing authorization application and available authorization procedures

Authorization to market a product in the EU member states proceeds under one of four procedures: a centralized authorization procedure, a mutual recognition procedure, a decentralized procedure or a national procedure.

- *Centralized authorization procedure.* A marketing authorization for certain drugs must be obtained through the centralized authorization procedure for marketing authorization, which, if granted, is automatically valid in all EU member states. The EMA and the EC administer the centralized authorization procedure.

Pursuant to Regulation 726/2004, this procedure is mandatory for:

- a) medicinal products developed by means of one of the following biotechnological processes:
 - recombinant DNA technology;
 - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells; and
 - hybridoma and monoclonal antibody methods;
- b) advanced therapy medicinal products as defined in Article 2 of Regulation 1394/2007 on advanced therapy medicinal products;
- c) medicinal products for human use containing a new active substance which, on the date of entry into force of this Regulation, was not authorized in the EU, for which the therapeutic indication is the treatment of any of the following diseases:
 - acquired immune deficiency syndrome;
 - cancer;
 - neurodegenerative disorder;
 - diabetes;
 - auto-immune diseases and other immune dysfunctions; and

· viral diseases; and

d) medicinal products that are designated as orphan medicinal products pursuant to Regulation 141/2000.

For these purposes, RRMS is treated as an auto-immune disease. Although we have built our regulatory plan on the understanding that use of the centralized authorization procedure will be mandatory for FP187 for use in RRMS, we have been advised that the application of the principles described above is not certain, and it is possible that FP187 could be approved for use in RRMS in the EU through the use of the alternative procedures described below.

The centralized authorization procedure is optional for other medicinal products if they contain a new active substance or if the applicant shows that the medicinal product concerned constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization is in the interest of patients at a European Community level.

Under the centralized authorization procedure, the CHMP serves as the scientific committee that renders opinions about the safety, efficacy and quality of human products on behalf of the EMA. The CHMP is composed of experts nominated by each member state's national drug authority, with one of them appointed to act as Rapporteur for the coordination of the evaluation with the possible assistance of a further member of the Committee acting as a Co-Rapporteur. After approval, the Rapporteur(s) continue to monitor the product throughout its life cycle. The CHMP has 210 days, to adopt an opinion as to whether a marketing authorization should be granted; the process usually takes longer as additional information is requested, which triggers delays in the procedural timelines. The process is complex and involves extensive consultation with the regulatory authorities of member states and a number of experts. Once the procedure is completed, a European Public Assessment Report, or EPAR, is produced. If the opinion is negative, information is given as to the grounds on which this conclusion was reached. The opinion produced by the CHMP is sent to the European Commission and used in reaching the final decision.

In general, if the centralized procedure is not followed, there are three alternative procedures:

· *Mutual recognition procedure.* If an authorization has been granted by one member state, or the reference member state, an application may be made for mutual recognition in one or more other member states, or the concerned member state(s).

· *Decentralized procedure.* The third option is the decentralized procedure. The decentralized procedure may be used to obtain a marketing authorization in several European member states when the applicant does not yet have a marketing authorization in any country.

· *National procedure.* Applicants following the national procedure will be granted a marketing authorization that is valid only in a single member state. Furthermore, this marketing authorization is not based on recognition of another marketing authorization for the same product awarded by an assessment authority of another member state. The national procedure can also serve as the first phase of a mutual recognition procedure.

It is not always possible for applicants to follow the national procedure. In the case of medicinal products in the category for which the centralized authorization procedure is compulsory, that procedure must be followed. In addition, the national procedure is not available in the case of medicinal product dossiers where the same applicant has already obtained marketing authorization in one of the other EU member states or has already submitted an application for marketing authorization in one of the other member states and the application is under consideration. In the latter case, applicants must follow a mutual recognition procedure.

In the event that we are not required to use the centralized procedure for FP187, we would consider using the decentralized procedure, as we believe it would afford us a faster pathway to approval. EU regulations allow for other approval procedures, some of which can shorten and simplify the approval process, but we have not included them in our regulatory planning, as we do not believe that they will be available for FP187.

After a drug has been authorized and launched, it is a condition of maintaining the marketing authorization that all aspects relating to its quality, safety and efficacy must be kept under review. Sanctions may be imposed for failure to adhere to the conditions of the marketing authorization. In extreme cases, the authorization may be revoked, resulting in withdrawal of the product from sale.

Period of authorization and renewals

Marketing authorization is valid for five years in principle and the marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization provides the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any authorization which is not followed by the actual placing of the drug on the EU market (in case of centralized procedure) or on the market of the authorizing member state within three years after authorization shall cease to be valid (the so-called sunset clause).

Regulatory data protection

Without prejudice to the law on the protection of industrial and commercial property, all applications for marketing authorization receive an 8+2+1 protection regime.

This regime consists of a regulatory data protection period of eight years plus a concurrent market exclusivity of ten years plus an additional market exclusivity of one further year if, during the first eight years of those ten years, the marketing approval holder obtains an approval for one or more new therapeutic indications which, during the scientific evaluation prior to their approval, are determined to bring a significant clinical benefit in comparison with existing therapies. Under the current rules, a third-party may reference the pre-clinical and clinical data of the original sponsor beginning eight years after first approval, but the third-party may market a generic version after only ten (or eleven) years have lapsed.

As indicated, additional data protection can be applied for when an applicant has complied with all requirements as set forth in an approved PIP.

Manufacturing

The manufacturing of authorized drugs, for which a separate manufacturer's license is mandatory, must be conducted in strict compliance with the EMA's cGMP requirements and comparable requirements of other regulatory bodies, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. The EMA enforces its cGMP requirements through mandatory registration of facilities and inspections of those facilities. The EMA may have a coordinating role for these inspections while the responsibility for carrying them out rests with the member states competent authority under whose responsibility the manufacturer falls. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and could subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action or possible civil and criminal penalties.

Marketing and promotion

The marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Community notably under Directive 2001/83 in the European Community code relating to medicinal products for human use as amended by Directive 2004/27. The applicable regulation aims to ensure that information provided by holders of marketing authorizations regarding their products is truthful, balanced and accurately reflects the safety and efficacy claims authorized by the EMA or by the competent authority of the authorizing member state. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

Pharmaceutical Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any drug products for which we obtain regulatory approval. Sales of FP187, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government health programs such as Medicare and Medicaid, commercial health insurers and managed care organizations. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. FP187 may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third-party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development.

The containment of healthcare costs has become a priority of governments, and the prices of drugs have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit. The U.S. government, state legislatures and non-U.S. governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Adoption of such controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals such as the product that we are developing and could adversely affect our net revenue and results.

Pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product to currently available therapies. For example, the EU provides options for its member states to restrict the range of drug products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a drug product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the drug product on the market. Other member states allow companies to fix their own prices for drug products, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. There can be no assurance that any country that has price controls or reimbursement limitations for drug products will allow favorable reimbursement and pricing arrangements for any of our products.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on drug pricing. Coverage policies, third-party reimbursement rates and drug pricing regulation may change at any time. In particular, the Patient Protection and Affordable Care Act was enacted in the United States in March 2010 and contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal health care programs. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Environmental, Health and Safety

Our operations are subject to a number of environmental acts and regulations. We believe that we are materially in compliance with all applicable environmental laws and regulations. Currently, there are no pending environmental issues that could have a material adverse effect on our business, financial position, results of operations and future growth prospects.

We consider it important to maintain a good working environment and comply with the regulatory requirements regarding working environment. This consists of the physical and psychological working environment, including heating, ventilation, air conditioning and air circulation and exhaust systems, as well as office furniture and equipment design and functionality, and other general health and safety systems, including control of the facility. We are from time to time subject to inspections by the Danish Working Environment Authority for compliance with the Danish Working Environment Act.

Facilities

Our corporate headquarters are located at Østergade 24A, 1, 1100 Copenhagen K, Denmark where we lease offices from two of our principal shareholders for administrative activities. In 2013, we paid DKK 465,564 (approximately \$83,000) for such premises. For more, see “Related Party Transactions – Leased Premises.”

Forward Pharma GmbH, our German wholly-owned subsidiary, has offices for administrative and operational activities in Leipzig, Germany. In 2013, we paid €20,087 (approximately \$27,000) for such premises.

We believe our facilities are suitable and adequate for our current needs.

Employees

We have two employees based in our headquarters in Copenhagen, Denmark, and we have five employees based in our office in Leipzig, Germany. All are employed on a part-time basis with the exception of one individual. None of our employees is represented by a labor union or covered under a collective bargaining agreement, and we have never experienced any work stoppages.

All other operational tasks are outsourced to consultant experts, such as formulation and QA/GMP experts, or consulting service companies, such as regulatory, patent and legal experts. We engage approximately 20 experts as consultants.

Insurance

We maintain all insurance coverage required under applicable law, including in relation to its research, pre-clinical and clinical development. In the future, we may or will be required to obtain additional insurance to cover potential product liability and other risks, which are inherent in the manufacturing, marketing and the commercialization and use of drugs.

We believe that we currently maintain appropriate insurance coverage, and that our current insurance coverage is in line with insurance coverage for comparable companies.

Legal Proceedings

We may, from time to time, become involved in legal proceedings in the ordinary course of business. We have not been a party to or paid any fees or damages in connection with any litigation, including any of our patent opposition actions pending before the EPO), that has had a material adverse effect on our business or financial position. Opposition proceedings against two of our European patents are currently pending and we are involved in an opposition proceeding in Europe against a Biogen patent. In addition, we are expecting an interference action involving one of our U.S. patents and one of Biogen’s patents to soon commence in the U.S. As a result of these activities, there can be no assurance that these patent proceedings might not evolve into more significant or costly matters, including related litigation, which proceedings or litigation could have a material adverse effect on our financial position. See “Risk Factors – Risks related to intellectual property – Biogen may initiate legal proceedings alleging that we are infringing its intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.”

MANAGEMENT

Executive Officers and Directors

The following table sets forth information regarding our executive officers and board of directors as of March 31, 2014. We are currently reviewing the composition of our executive officers and board of directors and our corporate governance practices in light of this offering and applicable requirements of the SEC and NASDAQ. In subsequent filings with the SEC, we will update any relevant disclosure as appropriate. We currently anticipate that we will appoint two directors who will fulfill the independence criteria required by NASDAQ prior to completion of this offering:

Name	Age	Position
Florian Schönharting	45	Chairman
Peder Møller Andersen	62	Chief Executive Officer and Chief Operating Officer
J. Kevin Buchi	59	Director
Torsten Goesch	54	Director

Florian Schönharting, Chairman

Mr. Schönharting is currently the chairman of our board of directors and has served on the board since the incorporation of the Company in July 2005. Mr. Schönharting is the co-founder of Forward Pharma. He has also founded or co-founded several other biopharmaceutical companies, including Genmab A/S, Veloxis A/S (f/k/a Life Cycle Pharma A/S) and Zealand Pharma A/S. Mr. Schönharting has a total over 22 years investment executive experience in public and private equity funds involved in the biopharmaceutical industry. He actively managed BI Healthcare SICAV and BI Bioteknologi SICAV for eight years. Mr. Schönharting currently manages the following funds: NB Public Equity K/S, Nordic Biotech K/S, Nordic Biotech Opportunity Fund K/S and NB FP Investment K/S. Mr. Schönharting has an M.Sc (Econ) from Copenhagen Business School.

Peder Møller Andersen, Chief Executive Officer and Chief Operating Officer

Dr. Andersen has served as our Chief Executive Officer and Chief Operating Officer since May 2012. He has been in charge of the clinical development program for FP187 at Forward Pharma since 2008 and also holds the position of Managing Director of Forward Pharma GmbH, Leipzig. Dr. Andersen has more than 25 years of experience in the pharmaceutical industry. He has also worked for CROs and small biopharmaceutical companies as an external consultant. Dr. Andersen also has several years of business development experience, generic and proprietary, in Europe with PLIVA, Croatia and AWD, Germany. He has also founded a successful Nordic-based pharmaceutical company. Dr. Andersen has degree from Copenhagen Medical School and trained in surgery, anesthesiology and internal medicine for 6 years.

J. Kevin Buchi, Director

Mr. Buchi has served on our board of directors since December 2012. He is the former CEO of Cephalon Inc., which was acquired by Teva Pharmaceutical Industries, or Teva, in 2011. He served as Corporate Vice President of Global Branded Products for Teva until May 2012. Mr. Buchi is also a member of the board of directors of Stemlime Therapeutics, a private biopharmaceutical company. Mr. Buchi has a Bachelor of Arts degree from Cornell University and a Master of Management degree from Northwestern University's J.L. Kellogg Graduate School of Management. He is also a Certified Public Accountant.

Torsten Goesch, Director

Dr. Goesch has served on our board of directors since June 2006. He has also been the director of Rosetta Capital, a secondary life sciences investor since 2002. In this function, Dr. Goesch was responsible for the management of several Rosetta capital investments and served as a member of the board of directors of many biopharmaceutical companies, including Enobia Ltd and Cytochroma Ltd. Dr. Goesch is also the founder and former Managing Director of TRG Invest, a Munich-based consulting business providing companies in the life science sector. Additionally, Dr. Goesch served as the General Manager for the German Speaking Countries at Biogen from 1997 to 1999, and before that was the Commercial Head of Merck KGaA's worldwide generics drug business, Merck Generics. He practiced as a physician of internal medicine at the University Hospital Hamburg-Eppendorf from 1988 to 1990, focusing on nephrology, immunology and oncology. Dr. Goesch has a Master of Management from Northwestern University's J.L. Kellogg Graduate School of Management, as well as an M.D. and Ph.D. from Heinrich Heine University Dusseldorf.

Composition and Practices of the Board of Directors

The board of directors has the overall responsibility for our corporate management. The board of directors determines our policies regarding business strategy, organization, accounting and finance, and the board of directors appoints and supervises our executive officers. The majority of the members of the board of directors must be directors who are not executive officers, and no executive officer may be chairman or vice-chairman of the board of directors. The chairman is elected among and by the directors.

According to the Articles of Association that will be effective upon consummation of this offering, the board of directors must consist of not less than three and not more than six members. All members of the board of directors are elected by our shareholders at the general meeting for one year terms. The board of directors plans to meet at least four times each year, and meetings can be called when deemed necessary by any of our directors or members of our executive officers or by our auditor.

The Danish Companies Act requires granting employees in Danish companies a right of representation on the board of directors in companies with at least 35 employees. This requirement does not currently apply to us as we only have seven employees.

The board of directors conducts its business in accordance with the Danish Companies Act and its own rules of procedure. The rules of procedure set out, among other things, that the board of directors shall establish our strategy, policies and activities to achieve its objective in accordance with the Articles of Association. It also establishes the responsibilities of the board of directors, e.g., that the board of directors shall ensure that our bookkeeping, accounting, asset management, information technology systems, budgeting and internal controls are properly organized. The rules of procedure also provide guidelines for the division of responsibilities between the board of directors, the executive officers and the audit committee. The rules of procedure may be amended by a simple majority vote of the board.

A majority of the directors must be present to constitute a quorum. Unless otherwise decided by the board of directors, decisions of the board of directors are decided by a simple majority of votes cast.

Management

Our executive officers are responsible for our day-to-day business and operations. Peder Møller Andersen is our Chief Executive Officer and Chief Operating Officer.

We are currently engaged in an active search for a Chief Financial Officer, or CFO. For more, see "Risk Factors – Risks Related to Our Business and Industry – Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel, including a Chief Financial Officer."

Board Committees

Audit Committee

We have an audit committee, which was established on _____, 2014, under our board of directors consisting of Messrs. _____ and _____. Since there are no specific requirements under Danish law on the composition of our audit committee, we do not comply with Rule 4350(d) of the NASDAQ Marketplace Rules that requires the audit committees of U.S. companies have a minimum of three independent directors. Each of Messrs. _____ and _____ does, however, satisfy the "independence" requirements of each of the NASDAQ Marketplace Rules and Section 10A(m)(3)(B)(i) of the Exchange Act.

The principal duties and responsibilities of our audit committee will be:

- making recommendations on the appointment and retention of our independent registered public accounting firm which will audit our consolidated financial statements, overseeing the independent registered accounting firm's work and advising on the determination of the independent registered accounting firm's compensation;
- reviewing in advance all audit services and non-audit services to be provided to us by our independent registered accounting firm;
- recommending procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- reviewing and discussing with management and our independent registered accounting firm the results of the annual audit;
- conferring with management and our independent registered accounting firm about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices;
- overseeing regulatory compliance and related matters; and
- reviewing related party transaction matters.

We do not have a compensation committee or a nominations committee, nor is independent director involvement required in the selection of director nominees or in the determination of executive compensation. Our home country practice differs from Rule 5605 of the NASDAQ Marketplace Rules regarding independent directors' involvement in these areas, because there are no specific requirements under applicable Danish law on the establishment of compensation committees or nominations committees, and neither are there any requirements under applicable Danish law on independent directors' involvement in the selection of director nominees nor in the determination of executive compensation.

Code of Business Conduct

In connection with this offering, we are adopting a written code of business conduct, or code of conduct, which outlines the principles of legal and ethical business conduct under which we do business. The code of conduct applies to all of our board members and employees. The full text of the code of conduct will be made available on our website at www.forward-pharma.com. This website address is included in this prospectus as an inactive textual reference only. The information and other content appearing on our website are not part of this prospectus. Any amendments or waivers from the provisions of the code of conduct will be made only after approval by our audit committee and will be disclosed on our website promptly following the date of such amendment or waiver.

Exemptions from Certain Corporate Governance Requirements of NASDAQ

- As a foreign private issuer, we are not required to have an audit committee comprised of at least three members. Our audit committee is comprised of two members.
- As a foreign private issuer, we are not required to adopt a formal written charter or board resolution addressing the process for the nomination of directors. We do not have a nominations committee, nor have we adopted a board resolution addressing the nominations process.

- As a foreign private issuer, we are not required to hold regularly scheduled board meetings at which only independent directors are present.
- As a foreign private issuer, no quorum requirement will apply to our meetings of shareholders.
- As a foreign private issuer, we are not required to obtain shareholder approval for material revisions to our share-based incentive plans.
- As a foreign private issuer, we are not required to solicit proxies or provide proxy statements to NASDAQ pursuant to NASDAQ corporate governance rules or Danish law. Consistent with Danish law and as provided in our bylaws, we will notify our shareholders of meetings with at least two weeks' but not more than four weeks' notice. This notification will contain, among other things, information regarding business to be transacted at the meeting. In addition, our bylaws provide that shareholders must give us not less than six weeks' advance notice to properly introduce any business at an annual meeting of shareholders.

Other than as noted above, we are in compliance with other NASDAQ corporate governance standards applicable to U.S. domestic issuers.

Compensation of Executive Officers and Board

For the year ended December 31, 2013, the aggregate compensation paid to our executive officers and members of our board of directors (including bonuses) was \$325,000. For the year ended December 31, 2013, we also granted warrants to our executive officers offering the ability to subscribe for up to 18,719 Class A shares of nominal DKK 1.00 at an exercise price of DKK 150 per share. The total amount set aside or accrued by us to provide pension, retirement or similar benefits for our executive officers and members of our board of directors for the year ended December 31, 2013 was \$0.

As of December 31, 2013, Dr. Andersen, our CEO and COO, had warrants to subscribe for 18,719 Class A shares of nominal DKK 1.00 at an exercise price of DKK 150 per share pursuant to a grant made on October 1, 2013; such warrants are expected to vest on September 30, 2014. Dr. Andersen also has 5,000 warrants to purchase Class A shares of nominal DKK 1.00 at an exercise price of DKK 100 per share pursuant to a grant made on January 1, 2010. Such warrants are expected to vest on January 1, 2016.

None of our directors are employees of Forward Pharma A/S or its subsidiary, Forward Pharma GmbH, and accordingly, we do not have any written agreements with them providing for benefits upon termination.

Service Agreements

We have entered into a written service agreement with our CEO and COO, Dr. Andersen. Prior to the consummation of this offering, we intend to enter into an amended and restated service agreement with Dr. Andersen which will contain provisions standard for a company in our industry regarding non-competition, confidentiality of information and assignment of inventions.

2014 Equity incentive plan

After the consummation of this offering, we intend to grant share-based incentive compensation to employees, consultants and non-employee directors pursuant to our 2014 Equity Incentive Compensation Plan, or Share Plan. The Share Plan will be approved by our board of directors and stockholders prior to the consummation of this offering. The purpose of the Share Plan is to assist us in attracting and retaining to our employees, consultants and non-employee directors by offering them a greater stake in our company's success and a closer identity with it, and to encourage ownership of our company's stock by such employees, consultants and non-employee directors.

Share Reserve and Limitations. We have reserved an aggregate number of our ordinary shares for issuance pursuant to the Share Plan. The maximum number of shares of common stock available for awards that may be granted to an individual participant during a single year is _____.

Eligibility. All of our employees, consultants and non-employee directors are eligible to receive awards under the Share Plan.

Administration. The Share Plan will be administered by a compensation committee appointed by our board of directors; provided that if no such committee is appointed, the Share Plan shall be administered by our board and all references in the Share Plan to the committee shall be deemed to refer to the board. The committee will have the power to: (i) select the employees, consultants and non-employee directors who will receive awards pursuant to the Share Plan; (ii) determine the type or types of awards to be granted to each participant; (iii) determine the number of ordinary shares to which an award will relate, the terms and conditions of any award granted under the Share Plan (including, but not limited to, restrictions as to vesting, transferability or forfeiture, exercisability or settlement of an award and waivers or accelerations thereof, and waivers of or modifications to performance conditions relating to an award, based in each case on such considerations as the committee shall determine) and all other matters to be determined in connection with an award; (iv) determine whether, to what extent, and under what circumstances an award may be canceled, forfeited, or surrendered; (v) determine whether, and to certify that, the performance goals to which the settlement of an award is subject are satisfied; (vi) correct any defect or supply any omission or reconcile any inconsistency in the Share Plan, and adopt, amend and rescind such rules and regulations as, in its opinion, may be advisable in the administration of the Share Plan; (vii) determine the effect, if any, of a change in control of our company upon outstanding awards; and (viii) construe and interpret the Share Plan and make all other determinations as it may deem necessary or advisable for the administration of the Share Plan. It may delegate some or all of its powers to any executive officer of our company or any other person, other than its authority to grant awards to certain specified executives.

Types of Awards. Awards that can be granted under the Share Plan include ordinary shares, deferred shares, restricted shares and options.

Ordinary Shares. For awards of ordinary shares, a participant receives a grant of ordinary shares that are not subject to any restrictions on transfer or other vesting conditions. Upon the grant date, the participant will have all of the customary rights of a stockholder with respect to such shares, including the right to vote such shares and to receive dividends with respect to such shares.

Deferred Shares. For awards of deferred shares, we agree to deliver, subject to certain conditions, a fixed number of our ordinary shares to the participant at the end of a specified deferral period or periods. During such period or periods, the participant will have no rights as a shareholder with respect to any such shares. No dividends will be paid with respect to deferred shares during the applicable deferral period, and the participant will have no future right to any dividend paid during such period.

Restricted Shares. For awards of restricted shares, a participant receives a grant of shares of our ordinary shares that are subject to certain restrictions, including forfeiture of such shares upon the occurrence of certain events. During the restriction period, holders of restricted shares will have the right to vote such shares. During the restriction period, any dividends or distributions paid with respect to any restricted shares shall be subject to the same restrictions as apply to such restricted shares and shall be paid to the participant only if and when the applicable restriction period lapses.

Share Options. Share options granted under the Share Plan may be either incentive stock options or non-qualified options. The exercise price of an option shall be determined by the committee, but must be at least 100% of the fair market value of our company's ordinary shares on the date of the grant (110% in the case of an incentive stock option granted to a 10% shareholder).

Effects of a Change in Control. Upon the occurrence of a change in control of our company, all awards shall vest in full without regard to the level of achievement of any applicable performance goals. In addition, the committee may, in its discretion: (i) cancel any outstanding options in exchange for a cash payment of an amount (including zero) equal to the difference between the then fair market value of the option less the applicable option price; (ii) after having given the participant a chance to exercise any vested outstanding options, terminate any or all of the participant's unexercised options; (iii) cause the surviving corporation to assume all outstanding options or replace all outstanding options with economically comparable awards; or (iv) take such other action as the committee shall determine appropriate; provided that such action shall substantially preserve the economic value of such options determined as of immediately prior to such change in control.

Effects of Certain Corporate Transactions. In the event of a stock dividend, recapitalization, forward or reverse stock split, reorganization, division, merger, consolidation, spin-off, combination, repurchase or share exchange, extraordinary or unusual cash distribution or other corporate transaction or event that affects our ordinary shares, the committee shall make equitable adjustments in (i) the number and kind of shares of ordinary shares which may thereafter be issued in connection with awards, (ii) the number and kind of ordinary shares issuable in respect of outstanding awards, (iii) the aggregate number and kind of ordinary shares available under the Share Plan, and (iv) the exercise or grant price relating to any award, or if deemed appropriate, the committee may also make provision for a cash payment with respect to any outstanding award.

Clawback. Any award granted under the Share Plan, including an award of ordinary shares, will be subject to mandatory repayment by the participant to our company pursuant to the terms of any company "clawback" or recoupment policy that is directly applicable to the Share Plan and set forth in an award agreement or as required by law to be applicable to the participant.

Transfer Restrictions. No award or other right or interest of a participant under the Share Plan may be assigned or transferred for any reason during the participant's lifetime, other than to us, and any attempt to do so shall be void and the relevant award shall be forfeited. Notwithstanding the foregoing, the committee may grant awards, other than incentive share options, that are transferable by the participant during his or her lifetime, but only to the extent specifically provided in the agreement entered into with such participant. No incentive share option shall be transferable other than by will or the laws of descent and distribution.

Warrants

Employee Warrants

As of the date of this Prospectus, our former and existing and key employees, board members and consultants hold an aggregate of 136,773 warrants to purchase Class A shares (which will be converted into warrants to purchase ordinary shares prior to the completion of this offering) of nominal DKK 1.00 at specified prices and a weighted average exercise price of DKK 152.8. The warrants are subject to a variety of terms and vesting schedules. The consummation of this offering will not constitute a change in control, which would result in any unvested warrant vesting automatically. Investors will experience dilution of their interests to the extent that shares are issued upon the exercise of the warrants.

Investor Warrants

As of the date of this Prospectus, all warrants held by investors have been exercised in accordance with the following:

- on March 17, 2014, Nordic Biotech Opportunity Fund K/S cancelled its shareholder loan with a principal value of DKK 13.8 million (\$2.5 million), which amount was used to offset the exercise price on an aggregate of 137,750 warrants to purchase Class A shares held by it at an exercise price of DKK 100 per share; and
- on March 17, 2014, Nordic Biotech Opportunity Fund K/S subscribed for 260 Class A shares by way of exercise of 260 warrants, at a subscription price of DKK 100 per share.

Insurance and Indemnification

In connection with this offering, we intend to enter into indemnification agreements with our executive officers and members of our board of directors, undertaking to indemnify them to the fullest extent permissible under Danish law, including with respect to liabilities resulting from this offering to the extent that these liabilities are not covered by insurance. In addition, we intend to enter into a new insurance policy which will insure our directors and executive officers for certain actions taken in their professional capacity, subject to specified exemptions.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to directors or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the ownership of our Class A shares and Class B shares as of March 31, 2014, by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding Class A shares or Class B shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

The number of Class A shares or Class B shares beneficially owned by each entity, person or director is determined in accordance with the rules of the SEC governing the beneficial ownership of securities, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which a person has sole or shared voting power or investment power as well as any shares that such person has the right to acquire within 60 days of March 31, 2014 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

The percentage of shares beneficially owned before the offering is computed on the basis of 1,736,540 of our Class A shares and 56,851 Class B shares outstanding as of March 31, 2014. The percentage of shares beneficially owned after the offering is based on the number of our ordinary shares to be outstanding after this offering, including the ordinary shares that we are selling in this offering, and assumes no exercise of the underwriters' over-allotment option. Shares that a person has the right to acquire within 60 days of March 31, 2014 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is Østergade 24A, 1, 1100 Copenhagen K, Denmark.

Name and address of beneficial owner	Shares beneficially owned prior to the Share Conversion and the offering				Percent of total voting power before the offering (1)	Shares beneficially owned after Share Conversion and the offering
	Class A		Class B			
	Shares	%	Shares	%		
5% Shareholders						
BML Healthcare I, LP	492,952	28.37	-	*	0.96	
Nordic Biotech K/S	680,141	39.15	-	*	1.32	
Nordic Biotech Opportunity Fund K/S	564,247	32.48	10,136	17.83	18.32	
NB FP Investment K/S*	-	-	46,715	82.17	82.17	
Directors and Executive Officers						
Peder M. Andersen (2)	5,000	*	-	*		
J. Kevin Buchi (3)	5,956	*	-	*		
Torsten Goesch	-	*	-	*		
Florian Schönharting (4)	1,244,388	71.63	56,851	100	99.04	
All directors and executive officers as a group (4 persons) (4)	1,255,344	71.80	56,851	100	99.04	

* Indicates beneficial ownership of less than 5% of the total outstanding Class A shares and Class B shares.

(1) Each Class A share has one vote and each Class B share has 875 votes. Following the Share Conversion each ordinary share will have one vote.

(2) Consists of 5,000 Class A shares issuable upon exercise of warrants to purchase Class A shares exercisable within 60 days of March 31, 2014. Dr. Andersen also holds warrants to purchase 18,719 Class A shares that are subject to vesting conditions not expected to occur within 60 days of March 31, 2014.

(3) Consists of 5,956 Class A shares issuable upon exercise of warrants to purchase Class A shares exercisable within 60 days of March 31, 2014. Mr. Buchi also holds warrants to purchase 9,360 Class A shares that are subject to vesting conditions not expected to occur within 60 days of March 31, 2014.

(4) Through his ownership of Tech Growth Invest ApS, Mr. Schönharting controls a majority of the partnership interests in (a) Nordic Biotech General Partner ApS (which is the general partner of both Nordic Biotech K/S and Nordic Biotech Opportunity Fund K/S) and (b) NB FP Investment Partner ApS (which is the general partner of NB FP Investment K/S) and therefore, Mr. Schönharting may be deemed to share beneficial ownership of the securities beneficially owned by Nordic Biotech K/S, Nordic Biotech Opportunity Fund K/S and BP FP Investment K/S. Mr. Schönharting disclaims beneficial ownership of such securities except to the extent of his pecuniary interest therein.

RELATED PARTY TRANSACTIONS

The following is a description of our related party transactions we have entered into since January 1, 2010 with any of our members of our board of directors, executive officers and the holders of more than 5% of our Class A shares and Class B shares.

Framework Agreement

Our principal shareholders, Nordic Biotech K/S, Nordic Biotech Opportunity Fund K/S, or NBOF, BML Healthcare I, L.P. and NB FP Investment K/S, or NBFPI, intend to enter into a framework agreement prior to the consummation of this offering and to which we may also become a party. Among other things, each of the corporate actions described below shall occur prior to (or in connection with) the consummation of this offering:

- We shall hold an extraordinary general meeting pursuant to which our shareholders will authorize our board of directors to issue new shares without pre-emption rights for our existing shareholders, which such shares shall be issued in the initial public offering; and
- Prior to our board's approval of the offer price and the allocation of ordinary shares offered by this Prospectus, we shall hold an extraordinary general meeting pursuant to which the Share Conversion will be authorized, where all of our outstanding Class A shares and Class B shares shall be converted into ordinary shares. The Share Conversion will be effectuated prior to consummation of this offering.

Shareholders' Agreement

On January 19, 2013, all of our existing shareholders entered into an amended shareholders' agreement, which was amended on September 18, 2013 and which will be terminated in connection with the consummation of this offering. The key terms of the shareholders' agreement are as follows:

- *Appointment of Board.* Providing NB FP Investments K/S, or NBFPI, with the right to appoint three directors (including the chairman), Nordic Biotech Opportunity Fund K/S, or NBOPP, and Nordic Biotech K/S, or NB, shall collectively have the right to appoint one director, and BML Healthcare I, L.P., or BML, shall have the right to appoint one director;
- *Supermajority Voting.* Requiring approval of certain key decisions by approval of at least 85% of the outstanding share capital, including redemptions of shares;
- *Veto rights of NBFPI.* Providing NBFPI with veto rights over certain key decisions including the annual business plan and budget, and certain significant transactions such as incurrence of indebtedness or investments in excess of DKK 200,000; and
- *Preemptive rights, drag- and tag-along rights.* Providing the shareholders with preemptive rights, and drag- and tag-along rights in certain situations.

Investment Agreement

We and each of our shareholders as of the date hereof are parties to an Investment Agreement dated January 19, 2013, pursuant to which NBFPI agreed to subscribe for up to 46,715 Class B shares of nominal DKK 1.00, at our request, at a subscription price of DKK 1,177.35 per share.

NBFPI subscribed for an aggregate of 46,715 Class B shares of nominal DKK 1.00 pursuant to the investment agreement, which consequently has no further force or effect.

New Shareholders' Agreement

In connection with the consummation of this offering, Nordic Biotech K/S, Nordic Biotech Opportunity Fund K/S, and NB FP Investment K/S currently holding an aggregate of 1,243,588 of our Class A shares and 56.851 of our Class B shares, representing 71.61 per cent of the Class A shares and all of the Class B shares outstanding as of March 31, 2014, will enter into a shareholders' agreement. The shareholders' agreement will contain customary shareholders' rights including rights with respect to registration of our ordinary shares owned by such shareholders.

Aditech Agreement

In 2004, a private Swedish company called Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech Advisors (an affiliate of one of our largest shareholders), began developing and filing patents for an innovative formulation and delivery system for DMF. In 2005 we entered into a patent license agreement with Aditech to license this patent family from Aditech, and in 2010 we acquired this patent family from Aditech pursuant to a patent transfer agreement. Under our agreements with Aditech, we obtained, among other things, Aditech's patents and associated know-how related to DMF formulations and delivery systems, subject to both diligence and minimum annual expenditure (€1.0 million per year) obligations on our part (with an option for Aditech to receive back, for no consideration, all of our DMF related assets should we fail to satisfy these obligations), as well as a payment by us to Aditech of up to 2% of net sales generated from our DMF products and processes. Further, our agreement with Aditech gives Aditech a 90-day right of first offer to acquire non-DMF related intellectual property assets we might choose to sell.

Convertible Shareholder Loan

We were the borrower under a convertible shareholder loan dated October 1, 2013 with Nordic Biotech Opportunity Fund K/S as lender, in the principal amount of DKK 13.8 million (\$2.5 million). The loan was cancelled, and in connection with such cancellation, the lender was issued 137,750 Class A shares, in March 2014. For more, see "Management – Investor warrants."

We were also the borrower under a convertible shareholder loan dated October 29, 2012 with Nordic Biotech Opportunity Fund K/S as lender, in the principal amount of DKK 11.7 million (\$2.1 million). The loan was cancelled, and in connection with such cancellation, the lender was issued 10,136 Class B shares, in January 2013.

For more, see "Management's Discussion and Analysis of Financial Condition and Results of Operations – Contractual obligations and commitments."

Leased Premises

We sublease our headquarters in Copenhagen, Denmark from the management company of two of its principal shareholders, Nordic Biotech K/S and Nordic Biotech Opportunity Fund K/S. In 2013, we paid DKK 465,564 (approximately \$83,000) for such premises. We also sublease our offices in Leipzig, Germany. In 2013, we paid €20,087 (approximately \$27,000) for such premises.

Indemnification Agreements

We intend to enter into indemnification agreements with members of our board of directors and our executive officers. The indemnification agreements require us to indemnify said persons to the fullest extent permitted by law. See "Management – Insurance and Indemnification" for a description of these indemnification agreements.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

General

We were incorporated on July 1, 2005 as a limited liability company under Danish law. Upon consummation of this offering, our legal name will remain Forward Pharma A/S.

We are registered with the Danish Business Authority under company registration number, or CVR, 28865880. Our corporate seat is in Copenhagen, Denmark, and our registered office is Østergade 24A, 1, 1100 Copenhagen K, Denmark.

As of the date of this prospectus, the issued and registered share capital of the Company is nominally DKK 1,793,391, divided into shares of DKK 1.00 each. Our share capital is divided into two share classes, being nominally DKK 1,736,540 Class A shares and nominally DKK 56,851 Class B shares. The share capital is fully paid up.

Prior to the consummation of this offering, all of our Class A and Class B shares will be converted into an aggregate of ordinary shares (after which we will only have one class of shares), pursuant to the Share Conversion.

We intend to apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol “FWP.”

Initial settlement of the ordinary shares issued in this offering will take place on the consummation date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning ordinary shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the ordinary shares.

Articles of Association

Our current Articles of Association, or Current Articles, were last amended on March 17, 2014. Under our Current Articles, our objective is to develop and market pharmaceuticals. We will, subject to completion of this offering, further amend our Current Articles in order to allow for the Share Conversion pursuant to which all of our outstanding Class A shares and Class B shares will be converted into ordinary shares prior to consummation of this offering.

Comparison of Danish Corporate Law and Our Articles of Association and U.S. Corporate Law

The following comparison between Danish corporation law and our Articles of Association, which applies to us, and Delaware corporation law, the law under which many publicly listed corporations in the United States are incorporated, discusses additional matters not otherwise described in this Prospectus. Although we believe this summary is materially accurate, the summary is subject to Danish law, including the Danish Companies Act and Delaware corporation law, including the Delaware General Corporation Law. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

Corporate governance

Duties of directors

Denmark. The board of directors is responsible for overall and strategic management. In addition to performing overall management duties and strategic management duties and ensuring proper organization of the company's business, the board must ensure that:

1. the bookkeeping and financial reporting procedures are satisfactory, having regard to the circumstances of the limited liability company;
2. adequate risk management and internal control procedures have been established;

3. the board of directors receives ongoing information as necessary about the limited liability company's financial position;
4. the executive board performs its duties properly and as directed by the board of directors; and that
5. the financial resources of the limited liability company are adequate at all times, and that the company has sufficient liquidity to meet its current and future liabilities as they fall due. The limited liability company is therefore required to continuously assess its financial position and ensure that the existing capital resources are adequate.

The board of directors must appoint an executive board to be responsible for the day-to-day management of the company. The executive board must either consist of one or more persons who are also members of the board of directors, or consist of persons who are not members of the board of directors. In both cases, persons in charge of day-to-day management will be designated as executive officers, and together they form the executive board of the limited liability company. The majority of the members of the board of directors of public limited companies must be non-executive directors. No executive officer in a public limited company may be chairman or vice-chairman of the board of directors of that company.

Delaware. The board of directors bears the ultimate responsibility for managing the business and affairs of a corporation. In discharging this function, directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. Delaware courts have decided that the directors of a Delaware corporation are required to exercise informed business judgment in the performance of their duties. Informed business judgment means that the directors have informed themselves of all material information reasonably available to them. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action in connection with a change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.

Director terms

Denmark. Under Danish law, directors are elected by the general meeting for the terms set out in the company's articles of association, provided however that the term shall expire with the closing of an annual general meeting held no later than four years after their election. Directors are usually elected for one-year terms. There is no limit in the number of terms a director may serve.

Delaware. The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the shareholders. A director elected to serve a term on a "classified" board may not be removed by shareholders without cause. There is no limit in the number of terms a director may serve.

Director vacancies

Denmark. Under Danish law, there is no obligation to fill vacancies, provided that the number of directors then in office corresponds to the interval set out in the articles of association and must be at least three members. Vacancies must otherwise be filled by election by the shareholders as soon as possible at a general meeting. Directors are elected by the shareholders by simple majority.

Delaware. The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of shares is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

Conflict-of-interest transactions

Denmark. Under the DCA, no member of management may participate in the transaction of business that involves any agreement between the limited liability company and that member, or legal proceedings against that member, or the transaction of business that involves any agreement between the limited liability company and a third-party, or legal proceedings against a third-party, if the member has a material interest in such business and that material interest could conflict with the interests of the limited liability company.

Delaware. The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director's relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director's relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the shareholders.

Proxy voting by directors

Denmark. A director of a Danish corporation may issue only to another director a proxy representing the director's voting rights as a director.

Delaware. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Shareholder rights

Voting rights

Denmark. Under Danish law each share is entitled to one vote unless otherwise provided for by the articles of association. Our Current Articles provide that each Class A share shall be entitled to one vote while each Class B share entitled to 875 votes. After the Share Conversion, our Articles of Association will provide for one class of shares, ordinary shares, and each ordinary share shall be entitled to one vote.

All business transacted by the general meeting shall be decided by a simple majority of votes, unless otherwise provided by the Danish Companies Act or by the articles of association.

A resolution to amend the Articles of Association requires that the resolution be adopted by at least two-thirds of the votes cast as well as the share capital represented at the general meeting, unless the Danish Companies Act or the articles of association requires a larger majority.

Delaware. Under the Delaware General Corporation Law, each shareholder is entitled to one vote per share, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one third of the shares entitled to vote at a meeting.

Shareholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the shareholders of record entitled to notice or to vote at a meeting of shareholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

Shareholder proposals

Denmark. The shareholders' rights to pass resolutions are exercised at the general meetings of the limited liability company. All shareholders, irrespective of voting rights, are entitled to attend and speak at general meetings.

General meetings must be held at the registered office of the limited liability company, unless the articles of association specify another place at which the meetings must or can be held. If special circumstances require it, a general meeting may, in isolated cases, be held elsewhere.

The annual general meeting must be held in time for the annual report adopted by the board of directors and the general meeting to reach the Danish Business Authority within five months from the end of the financial year, the time limit specified in the Financial Statements Act. The annual report must be submitted to the general meeting.

Extraordinary general meetings must be held upon request from the board of directors or the auditor elected by the general meeting. Shareholders that hold 5% of the share capital can request an extraordinary general meeting in writing. Extraordinary general meetings to consider specific issues must be convened within two weeks of receipt of a request to such effect.

Delaware. Delaware law does not specifically grant shareholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a shareholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may include a shareholder proposal in the corporation's proxy materials relating to an annual or special meeting in accordance with those rules.

Action by written consent

Denmark. Under Danish law, publicly listed companies cannot permit shareholders of a corporation to take action by written consent. However, unless otherwise provided by the company's articles of association, the board of directors may determine that in addition to a right to physically attend general meetings, shareholders may be given the right to attend electronically, including using electronic voting that does not require physical attendance at the meeting, so that the general meeting will be partly electronic. Moreover, the general meeting may resolve to hold general meetings electronically without any opportunity for parties to physically attend, so that the meeting is held by electronic means alone. A resolution to that effect must be recorded in the company's articles of association.

Delaware. Although permitted by Delaware law, publicly listed companies do not typically permit shareholders of a corporation to take action by written consent.

Appraisal rights

Denmark. The Danish Companies Act provides for certain shareholder appraisal rights in connection with certain mergers and demergers, and in relation to cross-border mergers also the right to demand payment in cash of the judicially determined fair value of the shareholder's shares.

Delaware. The Delaware General Corporation Law provides for shareholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the shareholder's shares, in connection with certain mergers and consolidations.

Shareholder suits

Denmark. Under Danish law any shareholder can commence civil proceedings to recover damages. Shareholders who commence such proceedings must pay the legal costs involved, but may have such costs reimbursed by the company to the extent that they do not exceed the amount recovered by the company as a result of the proceedings. Shareholders representing at least one-tenth of the share capital may oppose any resolution to grant the board of director's or management's exemption from liability and may also waive the right to take legal action against the board of directors and management board.

Delaware. Under the Delaware General Corporation Law, a shareholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated shareholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a shareholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a shareholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

Repurchase of shares

Denmark. Under Danish law, a limited liability company may acquire its own shares if they are fully paid up. The shares may be acquired both in ownership and by way of security. If a limited liability company acquires its own shares for consideration, such consideration may only consist of the funds that may be distributed as extraordinary dividends under the provisions of the Danish Companies Act and the company's holding of its own shares must be disregarded when assessing whether the company satisfies the mandatory minimum capital requirements. An acquisition of a company's own shares for consideration cannot proceed without the board of directors' obtaining authority from the general meeting, and such authority may only be given for a specified time, which may not exceed five years. The authority must specify (i) the maximum permitted value of the company's own shares; and (ii) the minimum and maximum amount that may be paid by the company as consideration for the shares.

Delaware. Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

Anti-takeover provisions

Denmark. Danish company law does not contain specific anti-takeover provisions for unlisted companies but a company's articles of association may include poison pills to this effect, e.g., share classes with higher voting rights than other share classes or provisions to the effect that the board of directors shall approve share transfers.

Delaware. In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits "business combinations," including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested shareholder that beneficially owns 15% or more of a corporation's voting shares, within three years after the person becomes an interested shareholder, unless:

- the transaction that will cause the person to become an interested shareholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested shareholder, the interested shareholder holds at least 85% of the voting shares of the corporation not including shares owned by persons who are directors and officers of interested shareholders and shares owned by specified employee benefit plans; or

after the person becomes an interested shareholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting shares, excluding shares held by the interested shareholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until twelve months following its adoption.

Inspection of books and records

Denmark. Under Danish law, the company's annual report is public and shareholders have no access to inspect the company's books and records. They are instead referred to exercise their right to ask questions to the board or management at a general meeting or to submit a proposal for scrutiny of the company's formation, of any specific matter relating to the administration of the company, or of certain financial statements. If such a proposal is adopted by a simple majority of votes, the general meeting must elect one or more scrutinizers. The scrutinizer may demand from the company's management any information deemed to be of importance to the assessment of the company and shall submit a written report to the general meeting.

Delaware. Under the Delaware General Corporation Law, any shareholder may inspect for any proper purpose certain of the corporation's books and records during the corporation's usual hours of business.

Removal of directors

Denmark. Under Danish law, members of the board of directors may be removed at any time by the electing or appointing party. Consequently, directors may be removed on general meetings by a simple majority of votes.

Delaware. Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, shareholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

Preemptive rights

Denmark. Under Danish law, existing shareholders will have preemptive rights to participate on the basis of their existing share ownership in the issuance of any new shares for cash consideration, unless those rights are waived by a resolution of the shareholder at a general meeting or the shares are issued on the basis of an authorization to the board of directors under which the board is granted the authority to waive the preemptive rights. Furthermore, the preemptive rights of the shareholders may be derogated from by a majority comprising at least two-thirds of the votes cast and of the share capital represented at the general meeting if the share capital increase is made at market price.

Delaware. Under the Delaware General Corporation Law, shareholders have no preemptive rights to subscribe for additional issues of shares or to any security convertible into such shares unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

Dividends

Denmark. Under Danish law, the company's assets may only be distributed to its shareholders (i) as dividends, based on the latest adopted financial statements; (ii) as extraordinary dividends; (iii) in connection with capital reductions; or (iv) in connection with the dissolution of the company.

The company's board of directors is responsible for ensuring that distributions do not exceed a reasonable amount having regard to the company's financial position and, for parent companies, the group's financial position, and that no distribution is made to the detriment of the company or its creditors.

The general meeting decides how to distribute, by ordinary dividend, the amount available for distribution as recorded in the financial statements. Dividends may only be distributed out of distributable reserves, which are amounts stated as retained earnings in the company's latest adopted financial statements, and reserves that are distributable under statute or the company's articles of association, less retained losses.

The general meeting may decide to distribute extraordinary dividends made up of the amounts referred to above and profit for the current financial year up to the date of the resolution on distribution if such profit has not been distributed, appropriated or tied up. Any resolution on the distribution of extraordinary dividends must be accompanied by a balance sheet. The board of directors must assess whether the balance sheet from the latest annual report is adequate, or whether an interim balance sheet showing that sufficient funds are available for distribution has to be prepared. Where a resolution on the distribution of extraordinary dividends shall be passed more than six months after the balance sheet date as set out in the company's latest adopted annual report an interim balance sheet must always be prepared showing that sufficient funds are available for distribution. The interim balance sheet shall be reviewed by the company's auditor.

Delaware. Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding shares of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including shares of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common stock, property or cash.

Shareholder vote on certain reorganizations

Denmark. Shareholders' approval rights may be (and often are) prescribed in the company's articles of association or in a shareholders' agreement, or both.

Mergers shall be resolved by the shareholders of the discontinuing company, whereas the board of directors is the competent body in the continuing company, provided that the merger does not require a capital increase or other amendments to the articles of association of the continuing company, in which case the merger must be approved by the shareholders.

Voluntary public tender offers are usually conditional upon the situation where a certain percentage of nominal share capital or voting rights (or both) of the target company accepts the offer, the percentage of which depends on the aim the bidder is seeking to achieve. Ordinary amendments of the articles of association require two-thirds of both votes and capital, while squeeze-out and delisting requires more than nine-tenths of both votes and capital.

The Danish Companies Act provides that a minority shareholder may demand that a single majority shareholder holding more than nine-tenths of both the shares and capital buys all of the shares of that minority shareholder.

Delaware. Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares capital entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the shares or of any class or series of shares than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the shareholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, shareholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the shareholders will be entitled to appraisal rights.

Remuneration of directors

Denmark. Under Danish law, the board of directors may receive fixed or variable remuneration. The amount of remuneration may not exceed what is considered usual, taking into account the nature and extent of the work, and what is considered reasonable with regard to the limited liability company's financial position and, in the case of parent companies, the group's financial position. Since the board of directors is disqualified to resolve remuneration on its own, the remuneration is fixed by the shareholders, typically at the ordinary general meeting in connection with the adoption of the company's annual report.

Delaware. Under the Delaware General Corporation Law, the shareholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of executive compensation may be subject to shareholder vote due to the provisions of U.S. federal securities and tax law, as well as exchange requirements.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no market for our Class A shares or Class B shares. Future sales of substantial amounts of our ordinary shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of ordinary shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our ordinary shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price of our ordinary shares and our ability to raise equity capital in the future.

Upon completion of this offering, we will have _____ ordinary shares outstanding, or _____ ordinary shares outstanding if the underwriters exercise their options in full to purchase additional ordinary shares. Of these shares,

_____ ordinary shares, or _____ ordinary shares if the underwriters exercise their options in full to purchase additional ordinary shares, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining ordinary shares are “restricted shares” as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

Number of Shares	Date
	On the date of this Prospectus.
	After 90 days from the date of this Prospectus (subject, in some cases, to volume limitations).
	After 180 days from the date of this Prospectus (subject, in some cases, to volume limitations).

Rule 144

In general, a person who has beneficially owned our ordinary shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our ordinary shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our ordinary shares then outstanding, which will equal approximately _____ ordinary shares immediately after this offering, assuming no exercise of the underwriters’ option to purchase additional shares; or
- the average weekly trading volume of our ordinary shares on NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this Prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this Prospectus, may be sold by persons other than “affiliates,” as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by “affiliates” under Rule 144 without compliance with its one-year minimum holding period requirement.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

Registration Rights

We intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Related Party Transactions – Registration Rights Agreement.”

Lock-Up Agreements

We and all of our directors and executive officers have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the ordinary shares or such other securities for a period of 180 days after the date of this Prospectus, subject to certain exceptions, without the prior written consent of Leerink Partners. See “Underwriting.”

TAXATION

The following summary contains a description of certain Danish and U.S. federal income tax consequences of the acquisition, ownership and disposition of ordinary shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase ordinary shares. The summary is based upon the tax laws of Danish and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.

Danish Tax Considerations

The following discussion is a summary of the material Danish tax considerations relating to the purchase, ownership and disposition of our ordinary shares.

Taxation in Denmark

The summary is for general information only and does not purport to constitute exhaustive tax or legal advice.

The information is summarized based on the tax laws of Denmark in effect and applied as at the date of this Prospectus and is subject to change as a result of changes in Danish legislation, including those that could have a retroactive effect, or new legislation. It is specifically noted that the description does not address all possible tax consequences of an investment in the ordinary shares offered by this Prospectus. Therefore, this summary may not be relevant, for example, to investors subject to the Danish Act on Pension Investment Return Taxation (i.e. pension savings) and professional investors, certain institutional investors, insurance companies, pension companies, banks, stockbrokers and individuals and companies carrying on business of purchasing and selling shares to whom special tax rules apply.

Prospective investors in the ordinary shares offered by this Prospectus are advised to consult their tax advisors regarding the applicable tax consequences of acquiring, holding and disposing of the Ordinary shares offered by this Prospectus based on their particular circumstances. Prospective investors who may be affected by the tax laws of other jurisdictions should also consult their tax advisors with respect to the tax consequences applicable to their particular circumstances as such consequences may differ significantly from those described herein.

The following summary is based on the Danish tax law as applied and interpreted by Danish tax courts and as published and in effect on the date hereof, without prejudice to any amendments introduced at a later date and implemented with or without retroactive effect.

For the purpose of this paragraph, “Danish Taxes” shall mean taxes of whatever nature levied by or on behalf of Denmark or any of its subdivisions or taxing authorities.

Taxation of shareholders resident in Denmark

Subscription of Offer Shares

The subscription for the Ordinary shares offered by this Prospectus has no tax effect.

Sale of Offer Shares – Individuals

Gains on the sale of listed shares are taxed as share income at a rate of 27% on the first DKK 49,200 in 2014 (for cohabiting spouses a total of DKK 98,400), and at a rate of 42% on share income over DKK 49,200 (for cohabiting spouses a total of DKK 98,400). All amounts are subject to annual adjustments, and include all share income derived by the individual or cohabiting spouses, respectively.

Gains and losses on the sale of listed shares are made up as the difference between the purchase price and the sales price. The purchase price is based on the average purchase price for the shares in that particular company. Losses on listed shares may only be offset against other income from listed shares, i.e. gains from the same or other listed shares and dividends received on such shares. Unused losses will be offset against a cohabiting spouse’s share income derived from listed shares. If a cohabiting spouse has no share income deriving from listed shares the losses can be carried forward indefinitely and offset against future share income deriving from listed shares.

Losses on listed shares may however only be offset against other share income derived from listed shares if the Danish Tax Authorities have received certain information concerning the shares. Such information is normally provided to the tax authorities by the securities dealer, if the securities dealer is Danish.

Sale of Offer Shares – Companies

A distinction is made between “Subsidiary Shares,” “Group Shares” and “Portfolio Shares” with respect to taxation of capital gains derived from the sale of the Ordinary shares offered by this Prospectus.

- “Subsidiary Shares” are generally defined as shares held by a shareholder with a direct holding of 10% or more of the share capital of a company.
- “Group Shares” are generally defined as shares held in a company in which the shareholder of the company and the company are jointly taxed or meet the criteria for international joint taxation, usually implying that they control, directly or indirectly, more than 50% of the votes.
- “Portfolio Shares” are shares not falling within the definitions of “Subsidiary Shares” or “Group Shares,” for example if the shareholder holds less than 10% (and the Shares are not Group Shares).

Capital gains derived from the sale of listed Portfolio Shares are taxable irrespective of the holding period at a rate of 24.5%. Such gain is taxed in accordance with the mark-to-market principle and the taxable gain is calculated at the end of each year as the difference between the market value of the shares at the beginning and end of the tax year. Thus, taxation will take place on an accrual basis even if no shares have been disposed of and no gains or losses have been realized. Capital gains derived from the sale of Subsidiary Shares and Group Shares are exempt from taxation, irrespective of the holding period.

Losses on Portfolio Shares are tax deductible. Losses on Subsidiary Shares and Group Shares are not tax deductible.

It should be noted that a change of status from Subsidiary Shares/Group Shares to Portfolio Shares and vice versa will be treated as a disposal of the shares and reacquisition at the market price of the shares at the relevant time.

Special anti-avoidance rules apply to certain holding companies holding Subsidiary Shares or Group Shares. These rules are not described herein.

Dividends – Individuals

Dividends paid to private individuals who are tax residents of Denmark are taxed as share income at the applicable rates. It must be noted that all share income must be included when calculating whether the amounts mentioned above are exceeded.

Dividends paid to individuals are generally subject to withholding tax, which is the responsibility of the company, at a rate of 27%.

Dividends – Companies

The distinction described above between “Subsidiary,” “Group Shares” and “Portfolio Shares,” as set forth in “Sale of Offer Shares – Companies” above, is also made with respect to taxation of dividends on shares.

Dividends paid to companies are generally subject to corporate tax at a rate of 22%. However, no corporate tax is levied on dividends derived from Subsidiary Shares and Group Shares. The 22% rate applies to dividends derived from Portfolio Shares.

Taxation of Shareholders Resident Outside Denmark

Subscription for Shares

The subscription for the Ordinary shares offered by this Prospectus has no tax effect.

Sale of Shares

A non-resident of Denmark, irrespective of whether the non-resident is a private individual or corporate shareholder, will normally not be subject to Danish tax on any capital gains realized on the sale of shares irrespective of the holding period. Where a non-resident of Denmark holds shares which can be attributed to a permanent establishment in Denmark, such gains are taxable pursuant to the rules applying to a Danish tax resident.

Dividends

Under Danish law, dividends paid in respect of shares are generally subject to Danish withholding tax at a rate of 27%, irrespective of whether the non-resident shareholder is a private individual or a company. Non-residents of Denmark are not subject to additional Danish income tax in respect of dividends received on the shares.

With respect to dividends distributed to a foreign company, no tax is withheld on dividends derived from Subsidiary Shares or Group Shares as defined in “Taxation of Shareholders Resident in Denmark – Sale of Offer Shares – Companies” above, provided that the withholding tax on dividends is eliminated or reduced according to Council Directive 90/435/EEC (EU Parent Subsidiary Directive) or a double tax treaty with the jurisdiction in which the dividend receiving company is resident. With respect to Group Shares, it is also a requirement that the company receiving the dividends is a resident of an EU or EEA country and that withholding taxes on dividends would have been eliminated or reduced according to Council Directive 90/435/EEC (EU Parent Subsidiary Directive) or a double tax treaty with the jurisdiction in which the dividend receiving company is resident if the Group Shares had been Subsidiary Shares.

In the event that the dividend-receiving individual or company owns less than 10% of the shares in the company distributing the dividends and the shareholder is a resident of a state with which Denmark has entered into a double taxation treaty or another arrangement for the exchange of information between the countries’ tax authorities, such dividends are subject to Danish tax at a rate of 27%. However, in case of specific tax treaty grants a lower withholding tax than 27%, the recipient must request a refund of Danish tax withheld in excess of the lower rate set forth in the applicable double tax treaty. Where the recipient is tax resident in a country outside the EU, but in a country that has entered into an agreement on exchange of information with Denmark, it is an additional condition that the recipient together with associated parties does not own more than 10% of the shares in the Danish company paying the dividends.

Denmark has executed double tax treaties with approximately 80 countries, including the United States and almost all members of the EU. If Denmark has entered into a double tax treaty with the country in which the shareholder is resident, the shareholder may, through certain certification procedures, seek a refund from the Danish tax authorities of the tax withheld in excess of the tax (typically 15%) to which Denmark is entitled under the relevant tax treaty, by completing the relevant tax form and filing it with the Danish Tax Authorities. The treaty between Denmark and the United States generally provides for a 15% rate.

In addition there is a special tax regime that applies to dividends, distributed to individuals resident in certain countries, such as the United States, the United Kingdom, Belgium, Canada, Greece, the Netherlands, Ireland, Luxembourg, Norway, Switzerland, Sweden and Germany. This special tax regime provides that tax on dividends may be withheld at the applicable tax rate specified in the relevant double tax treaty. In order to qualify for the application of this special tax regime, an eligible holder of shares must deposit his shares with a Danish bank, and the shareholding must be registered with and administered through VP Securities. In addition, such shareholders must provide documentation from the relevant foreign tax authority as to the shareholder’s tax residence and eligibility under the relevant double tax treaty. A special form prepared by the Danish tax authorities must be filed by the eligible holder of shares in order to take advantage of this special tax regime. If documentation is not filed before dividends are paid, a refund of excess withholding tax may be sought pursuant to the description in the preceding paragraph.

Share Transfer Tax

No Danish share transfer tax is payable.

U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of ordinary shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that holds ordinary shares as capital assets for tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Code known as the net investment income tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the ordinary shares;
- regulated investment companies;
- real estate investment trusts, grantor trusts or other trusts;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- expatriates of the United States;
- tax exempt entities, including "individual retirement accounts" and "Roth IRAs";
- entities classified as partnerships for U.S. federal income tax purposes;
- persons that own or are deemed to own ten percent or more of our voting shares; and
- persons holding ordinary shares in connection with a trade or business conducted outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares and partners in such partnerships are encouraged to consult their own tax advisers as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed U.S. Treasury Regulations, and the income tax treaty between Denmark and the United States, or the Treaty, all as of the date hereof, changes to any of which may affect the tax consequences described herein—possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares who is eligible for the benefits of the Treaty and is:

- (1) an individual who is a citizen or resident of the United States;
- (2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;
- (3) an estate whose income of which is subject to U.S. federal income tax regardless of its source; or
- (4) a trust, if (A) a U.S. court is able to exercise its primary supervision over the trust's administration and one or more United States persons (as such term is defined under the Code) have authority to control all substantial decisions of the trust, or (B) the trust has a valid election in place under all applicable U.S. Treasury regulations to treat the trust as a United States person (as such term is defined under the Code).

U.S. Holders are encouraged to consult their own tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of ordinary shares in their particular circumstances.

TO ENSURE COMPLIANCE WITH U.S. INTERNAL REVENUE SERVICE CIRCULAR 230, PROSPECTIVE INVESTORS ARE HEREBY NOTIFIED THAT: (I) ANY DISCUSSION OF U.S. FEDERAL TAX ISSUES CONTAINED OR REFERRED TO IN THIS PROSPECTUS IS NOT INTENDED OR WRITTEN TO BE USED, AND CANNOT BE USED, BY PROSPECTIVE INVESTORS FOR THE PURPOSE OF AVOIDING PENALTIES THAT MAY BE IMPOSED ON THEM UNDER THE CODE; (II) SUCH DISCUSSION IS WRITTEN IN CONNECTION WITH THE PROMOTION OR MARKETING OF THE TRANSACTIONS OR MATTERS ADDRESSED HEREIN; AND (III) PROSPECTIVE INVESTORS SHOULD SEEK ADVICE BASED ON THEIR PARTICULAR CIRCUMSTANCES FROM AN INDEPENDENT TAX ADVISOR.

Taxation of distributions

Subject to the PFIC rules described below, distributions paid on ordinary shares, other than certain pro rata distributions of ordinary shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to long-term capital gain. The amount of a dividend will include any amounts withheld by us in respect of Danish income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in Euros will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, Danish income taxes withheld from dividends on ordinary shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any Danish income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or other taxable disposition of ordinary shares

Subject to the PFIC rules described below, gain or loss realized on the sale or other taxable disposition of ordinary shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

Passive Foreign Investment Company rules

Under the Code, we will be a PFIC for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consist of assets that produce, or are held for the production of, "passive income." Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains. Whether we will be a PFIC in any year depends on the composition of our income and assets, and the relative fair market value of our assets from time to time, which we expect may vary substantially over time. Because (i) we currently own, and will own after the completion of this offering, a substantial amount of passive assets, including cash, and (ii) the values of our assets, including our intangible assets, that generate non-passive income for PFIC purposes, is uncertain and may vary substantially over time, it is uncertain whether we will be, and there can be no assurance that we will not be a PFIC in 2014 or any future year. If we are a PFIC for any year during which a U.S. Holder holds ordinary shares, we generally would continue to be treated as a PFIC with respect to that U.S. Holder for all succeeding years during which the U.S. Holder holds ordinary shares, even if we ceased to meet the threshold requirements for PFIC status.

If we are a PFIC for any taxable year during which a U.S. Holder holds ordinary shares, the U.S. Holder may be subject to adverse tax consequences. Generally, gain recognized upon a disposition (including, under certain circumstances, a pledge) of ordinary shares by the U.S. Holder would be allocated ratably over the U.S. Holder's holding period for such shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC would be taxed as ordinary income. The amount allocated to each other taxable year would be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and would be increased by an additional tax equal to interest on the resulting tax deemed deferred with respect to each such other taxable year. Further, to the extent that any distribution received by a U.S. Holder on its ordinary shares exceeds 125% of the average of the annual distributions on such ordinary shares received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, that distribution would be subject to taxation in the same manner described immediately above with respect to gain on disposition.

Alternatively, if we are a PFIC and if our ordinary shares are "regularly traded" on a "qualified exchange," a U.S. Holder could make a mark-to-market election that would result in tax treatment different from the general tax treatment described in the preceding paragraph. Our ordinary shares would be treated as "regularly traded" in any calendar year in which more than a *de minimis* quantity of the ordinary shares are traded on a qualified exchange on at least 15 days during each calendar quarter. NASDAQ is a qualified exchange for this purpose. If a U.S. Holder makes the mark-to-market election, the U.S. Holder generally will recognize as ordinary income any excess of the fair market value of the ordinary shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the ordinary shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the U.S. Holder's tax basis in the ordinary shares will be adjusted to reflect these income or loss amounts. Any gain recognized on the sale or other disposition of ordinary shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

A timely election to treat a PFIC as a qualified electing fund under Section 1295 of the Code would result in alternative treatment. U.S. Holders should be aware, however, that we do not intend to satisfy the record-keeping and other requirements that would permit U.S. Holders to make qualified electing fund elections if we were a PFIC.

In addition, if we are a PFIC or, with respect to particular U.S. Holders, are treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a U.S. Holder owns ordinary shares during any year in which we are a PFIC, the holder generally must file an IRS Form 8621, generally with the holder's federal income tax return for that year.

U.S. Holders should consult their tax advisers regarding whether we are or may become a PFIC and the potential application of the PFIC rules.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Certain U.S. Holders who are individuals may be required to report information relating to their ownership of an interest in certain foreign financial assets, including shares of a non-U.S. person, generally on Form 8938, subject to exceptions (including an exception for shares held through a U.S. financial institution). U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to ordinary shares.

UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement dated the date of this Prospectus among us and the underwriters named below, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase from us, the number of ordinary shares listed next to its name in the following table. Leerink Partners LLC is acting as sole book-running manager for the offering and as representative of the underwriters.

Name	Number of Shares
Leerink Partners LLC	
Total	

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the ordinary shares sold under the underwriting agreement if they purchase any of the ordinary shares. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the ordinary shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Discounts and Commissions

The underwriters propose initially to offer our ordinary shares to the public at the public offering price set forth on the cover page of this Prospectus and to dealers at that price less a concession not in excess of \$ _____ per share. After the initial offering of our ordinary shares, the public offering price and other selling terms may be changed by the representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

	Per Share	Without Option	With Option
Public Offering Price	\$ _____	\$ _____	\$ _____
Underwriting discounts and commissions	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____	\$ _____

The total estimated expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, are approximately \$ _____ million and are payable by us.

Over-Allotment Option

We have granted an option to the underwriters, exercisable for 30 days after the date of this Prospectus, to purchase up to _____ additional ordinary shares at the public offering price, less the underwriting discount. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

Initial Public Offering Pricing

Prior to this offering, there has been no public market for our ordinary shares. The initial public offering price will be determined through negotiations between us and the representative. Among the factors considered in these negotiations are:

- the prospects for our company and the industry in which we operate;
- our past and present financial and operating performance;
- financial and operating information and market valuations of publicly traded companies engaged in activities similar to ours;
- the prevailing conditions of U.S. securities markets at the time of this offering; and
- other factors deemed relevant.

The estimated initial public offering price range set forth on the cover of this preliminary prospectus is subject to change as a result of market conditions and other factors.

Lock-Up Agreements

We, our executive officers and directors have agreed not to sell or transfer any of our equity securities or securities convertible into or exchangeable or exercisable for our equity securities, for 180 days after the date of this Prospectus without first obtaining the written consent of the representative. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any of our equity securities;
- sell any option or contract to purchase any of our equity securities;
- purchase any option or contract to sell any of our equity securities;
- grant any option, right or warrant for the purchase or sale of any of our equity securities;
- lend or otherwise dispose of or transfer any of our equity securities;
- request or demand that we file a registration statement related to any of our equity securities; or
- enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of any of our equity securities, whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to equity securities of our company owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The lock-up does not apply to (i) the conversion of currently outstanding equity securities of our company into another class or series of equity securities of our company, (ii) the conversion of currently outstanding warrants exercisable for equity securities of our company into warrants exercisable for another class or series of equity securities of our company, (iii) the conversion of notes convertible into equity securities of our company into equity securities of our company, or (iv) the exercise of currently outstanding warrants to purchase equity securities of our company into equity securities of our company, in each case, prior to or upon consummation of this offering.

NASDAQ Listing

We anticipate that we will apply to have our ordinary shares listed on the NASDAQ Global Market under the symbol “FWP.”

Price Stabilization, Short Positions and Penalty Bids

In order to facilitate the offering of our ordinary shares, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of our ordinary shares. In connection with the offering, the underwriters may purchase and sell our ordinary shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of ordinary shares than they are required to purchase in the offering. “Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional ordinary shares in the offering. The underwriters may close out any covered short position by either exercising their over-allotment option or purchasing ordinary shares in the open market. In determining the source of ordinary shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. “Naked” short sales are sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing ordinary shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our ordinary shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of ordinary shares made by the underwriters in the open market prior to the completion of the offering.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our Class A shares or preventing or retarding a decline in the market price of our ordinary shares. As a result, the price of our ordinary shares may be higher than the price that might otherwise exist in the open market.

The underwriters have advised us that, pursuant to Regulation M under the Exchange Act, they may also engage in other activities that stabilize, maintain or otherwise affect the price of our ordinary shares, including the imposition of penalty bids. This means that if the representative of the underwriters purchases ordinary shares in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

The underwriters make no representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our ordinary shares. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that these transactions, once commenced, will not be discontinued at any time without notice.

Electronic Offer, Sale and Distribution of Ordinary Shares

A prospectus in electronic format may be made available on the websites maintained by one or more underwriters or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of ordinary shares to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the representative to underwriters and selling group members that may make Internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters’ websites and any information contained in any other website maintained by the underwriters is not part of this Prospectus or the registration statement of which this Prospectus forms a part.

Other Relationships

From time to time, certain of the underwriters and their affiliates have provided, and may provide in the future, various advisory, investment and commercial banking and other services to us in the ordinary course of business, for which they have received and may continue to receive customary fees and commissions.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, a Relevant Member State, with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State – the Relevant Implementation Date – our ordinary shares will not be offered to the public in that Relevant Member State prior to the publication of a prospectus in relation to the ordinary shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of ordinary shares may be made to the public in that Relevant Member State at any time:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the manager for any such offer; or
- (c) in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3(2) of the Prospectus Directive.

For the purposes of this provision, the expression an “offer of ordinary shares to the public” in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in each Relevant Member State and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

Our ordinary shares may not be offered or sold and will not be offered or sold to any persons in the United Kingdom other than persons whose ordinary activities involve them in acquiring, holding, managing or disposing of investments (as principal or as agent) for the purposes of their businesses and in compliance with all applicable provisions of the Financial Services and Markets Act 2000 (“FSMA”) with respect to anything done in relation to our common stock in, from or otherwise involving the United Kingdom.

In addition, each underwriter:

- (a) has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling with Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to the company; and
- (b) has complied with, and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the shares in, from or otherwise involving the United Kingdom.

Notice to Canadian Residents

Resale Restrictions

The distribution of our ordinary shares in Canada is being made only on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of ordinary shares are made. Any resale of our ordinary shares in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of our ordinary shares.

Representations of Purchasers

By purchasing our ordinary shares in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase our ordinary shares without the benefit of a prospectus qualified under those securities laws;
- where required by law, the purchaser is purchasing as principal and not as agent;
- the purchaser has reviewed the text above under “Resale Restrictions”; and
- the purchaser acknowledges and consents to the provision of specified information concerning the purchase of our ordinary shares to the regulatory authority that by law is entitled to collect the information, including certain personal information.

Rights of Action—Ontario Purchasers Only

Under Ontario securities legislation, certain purchasers who purchase our ordinary shares offered by this Prospectus during the period of distribution will have a statutory right of action for damages, or while still the owner of the ordinary shares, for rescission against us in the event that this Prospectus contains a misrepresentation without regard to whether the purchaser relied on the misrepresentation. The right of action for damages is exercisable not later than the earlier of 180 days from the date the purchaser first had knowledge of the facts giving rise to the cause of action and three years from the date on which payment is made for the ordinary shares. The right of action for rescission is exercisable not later than 180 days from the date on which payment is made for the ordinary shares. If a purchaser elects to exercise the right of action for rescission, the purchaser will have no right of action for damages against us. In no case will the amount recoverable in any action exceed the price at which our ordinary shares were offered to the purchaser and if the purchaser is shown to have purchased our ordinary shares with knowledge of the misrepresentation, we will have no liability. In the case of an action for damages, we will not be liable for all or any portion of the damages that are proven to not represent the depreciation in value of our ordinary shares as a result of the misrepresentation relied upon. These rights are in addition to, and without derogation from, any other rights or remedies available at law to an Ontario purchaser. The foregoing is a summary of the rights available to an Ontario purchaser. Ontario purchasers should refer to the complete text of the relevant statutory provisions.

Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein are located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

Taxation and Eligibility for Investment

Canadian purchasers of ordinary shares should consult their own legal and tax advisors with respect to the tax consequences of an investment in our ordinary shares in their particular circumstances and about the eligibility of our ordinary shares for investment by the purchaser under relevant Canadian legislation.

EXPENSES OF THE OFFERING

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

Expenses	Amount (USD)
U.S. Securities and Exchange Commission registration fee	*
FINRA filing fee	*
NASDAQ listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	*

* To be filed by amendment.

All amounts in the table are estimates except the U.S. Securities and Exchange Commission registration fee, the NASDAQ listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

LEGAL MATTERS

The validity of our ordinary shares and certain other matters of Danish law will be passed upon for us by Nielsen Nørager Law Firm LLP, Copenhagen. Certain matters of U.S. federal and New York State law will be passed upon for us by Dechert LLP, New York, New York. The underwriters have been represented in connection with this offering by K&L Gates LLP, Irvine, California.

EXPERTS

The consolidated financial statements of Forward Pharma A/S at December 31, 2013 and 2012 and January 1, 2012 and for each of the two years in the period ended December 31, 2013 appearing in this Prospectus and Registration Statement have been audited by Ernst & Young P/S, an independent registered public accounting firm, as set forth in their report thereon (which contains an explanatory paragraph describing conditions that raise substantial doubt about the Company's ability to continue as a going concern as described in note 2.1 to the consolidated financial statements) appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

The current address of Ernst & Young P/S Godkendt Revisionspartnerselskab is Gyngemose Parkvej 50, 2860 Søborg, Denmark.

ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of Denmark. Substantially all of our assets are located outside the United States. The majority of our managing directors and supervisory directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of the United States.

The United States and Denmark do not have a treaty providing for reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. Accordingly, a final judgment for the payment of money rendered by a United States court based on civil liability will not be directly enforceable in Denmark. However, if the party in whose favor such final judgment is rendered brings a new lawsuit in a competent court in Denmark, that party may submit to the Danish court the final judgment that has been rendered in the United States. A judgment by a federal or state court in the United States will neither be recognized nor enforced by a Danish court, but such judgment may serve as evidence in a similar action in a Danish court.

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against us or members of our board of directors, officers or certain experts named herein who are residents of Denmark or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This Prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this Prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send the transfer agent a copy of all notices of shareholders' meetings and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

Forward Pharma A/S

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Forward Pharma A/S

We have audited the accompanying consolidated statements of financial position of Forward Pharma A/S as of December 31, 2013, 2012 and January 1, 2012, and the related consolidated statements of comprehensive loss, changes in shareholders' equity, and cash flows for the two years in the period ended December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Forward Pharma A/S at December 31, 2013, 2012, and January 1, 2012 and the consolidated results of its operations and its cash flows for the two years in the period ended December 31, 2013, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2.1 to the consolidated financial statements, the Company has recurring losses from operations and an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Its ability to continue to operate is dependent upon obtaining additional financial support. Management's plans in regard to these matters are also described in Note 2.1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Ernst & Young P/S
Godkendt Revisionspartnerselskab
Copenhagen, Denmark
April 8, 2014

Christian Schwenn Johansen
State Authorised Public Accountant

Consolidated statement of financial position

Assets

	Notes	December 31,		January 1,
		2013	2012	2012
		USD'000	USD'000	USD'000
Property, plant and equipment	3.1	5	7	3
Total non-current assets		5	7	3
Other receivables	3.2	332	109	1,100
Income tax receivable	2.6	100	0	0
Prepayments		207	26	17
Cash and cash equivalents		2,955	828	427
Total current assets		3,594	963	1,544
Total assets		3,599	970	1,547

	Notes	December 31,		January 1,
		2013	2012	2012
		USD'000	USD'000	USD'000
Equity and liabilities				
Share capital		287	278	266
Share premium		26,697	16,637	14,794
Foreign currency translation reserve		-1,486	-369	0
Accumulated deficit		-51,913	-36,796	-14,775
Equity attributable to equity holders of the parent	4.1	-26,415	-20,250	285
Total equity		-26,415	-20,250	285
Interest-bearing convertible loans	4.4	0	2,100	0
Non-current liabilities		0	2,100	0
Interest-bearing convertible loans	4.4	2,613	0	0
Trade and other payables	3.3	1,277	750	289
Net settlement obligation to shareholder warrants	4.4	26,124	18,370	973
Current liabilities		30,014	19,120	1,262
Total liabilities		30,014	21,220	1,262
Total equity and liabilities		3,599	970	1,547

See accompanying notes to these consolidated financial statements

Consolidated statement of profit or loss

	<u>Notes</u>	Year end December 31,	
		<u>2013</u>	<u>2012</u>
		USD'000	USD'000
Research and development costs	2.4, 2.5, 3.1	-8,018	-4,445
General and administrative costs	2.4, 3.1	-1,014	-928
Operating loss		-9,032	-5,373
Fair value adjustment to net settlement obligation to shareholder warrants	4.4	- 6,676	-17,071
Other finance costs	4.3	-84	-35
Net loss before tax		-15,792	-22,479
Income tax benefit	2.6	96	0
Net loss for the year		-15,696	-22,479
Attributable to:			
Equity holders of the parent		-15,696	-22,479
		-15,696	-22,479
<i>Net loss per share:</i>	2.7		
Basic loss for the year per share		-9.53	-14.25
Diluted loss for the year per share		-9.53	-14.25

See accompanying notes to these consolidated financial statements

Consolidated statement of other comprehensive loss

	<u>Notes</u>	Year end December 31,	
		2013	2012
		<u>USD'000</u>	<u>USD'000</u>
Net loss for the year		<u>-15,696</u>	<u>-22,479</u>
Other comprehensive loss			
<i>Other comprehensive loss to be reclassified to profit or loss in subsequent periods:</i>			
Exchange differences on translation of foreign operations		<u>-1,117</u>	<u>-369</u>
Net other comprehensive loss to be reclassified to profit or loss in subsequent periods		<u>-1,117</u>	<u>-369</u>
Other comprehensive loss for the year, net of tax		<u>-1,117</u>	<u>-369</u>
Total comprehensive loss for the year, net of tax		<u>-16,813</u>	<u>-22,848</u>
Attributable to:			
Equity holders of the parent		<u>-16,813</u>	<u>-22,848</u>
		<u>-16,813</u>	<u>-22,848</u>

See accompanying notes to these consolidated financial statements

Consolidated statement of changes in shareholders' equity

	Notes	Share capital USD'000	Share premium USD'000	Foreign currency translation reserve USD'000	Accumulated deficit USD'000	Total equity USD'000
2012						
At January 1, 2012		266	14,794	0	-14,775	285
Net loss for the year		0	0	0	-22,479	-22,479
Other comprehensive loss		0	0	-369	0	-369
Total comprehensive loss		0	0	-369	-22,479	-22,848
Issue of share capital for cash	4.1	12	1,852	0	0	1,864
Costs related to capital increases		0	-9	0	0	-9
Share-based payment costs	2.5	0	0	0	458	458
Transactions with owners		12	1,843	0	458	2,313
At December 31, 2012		278	16,637	-369	-36,796	-20,250
2013						
At January 1, 2013		278	16,637	-369	-36,796	-20,250
Net loss for the year		0	0	0	-15,696	-15,696
Other comprehensive loss		0	0	-1,117	0	-1,117
Total comprehensive loss		0	0	-1,117	-15,696	-16,813
Issue of share capital for cash	4.1	7	7,944	0	0	7,951
Conversion of interest-bearing convertible loans to share capital	4.1	2	2,126	0	0	2,128
Costs related to capital increases		0	-10	0	0	-10
Share-based payment costs	2.5	0	0	0	579	579
Transactions with owners		9	10,060	0	579	10,648
At December 31, 2013		287	26,697	-1,486	-51,913	-26,415

See accompanying notes to these consolidated financial statements

Consolidated statement of cash flows

	<u>Notes</u>	Year ended December 31,	
		2013	2012
		USD'000	USD'000
Net loss before tax		-15,792	-22,479
<i>Adjustments to reconcile loss before tax to net cash flow:</i>			
Fair value adjustment to net settlement obligation to shareholder warrants		6,676	17,071
Other finance costs		84	35
Share-based payment costs		579	458
Depreciation charge for the year		4	2
Change in other receivables and prepayments		-370	812
Change in trade and other payables		446	607
Net cash flows used in operating activities		-8,373	-3,494
Investing activities			
Purchase of property, plant and equipment	3.1	0	-5
Net cash flows used in investing activities		0	-5
Financing activities			
Proceeds from issuance of interest-bearing convertible loans	4.1	2,456	2,030
Shares issued for cash	4.1	7,951	1,864
Transaction costs of capital increase		-10	-9
Net cash flows from financing activities		10,397	3,885
Net increase in cash and cash equivalents		2,024	386
Net foreign exchange differences		103	15
Cash and cash equivalents at January 1		828	427
Cash and cash equivalents at December 31		2,955	828

See accompanying notes to these consolidated financial statements

Corporate information

Forward Pharma A/S, or the Company, is a limited liability company incorporated and domiciled in Denmark. The registered office is located in Copenhagen, Denmark. The consolidated financial statements of the Company and Forward Pharma GmbH, its wholly-owned German subsidiary, or the Subsidiary, (collectively, the Group) for the years ended December 31, 2013 and 2012 were authorized for issue in accordance with a resolution of the directors on April 8, 2014.

The Company is a Danish biopharmaceutical company preparing to initiate a Phase 3 clinical trial using FP187, a proprietary formulation of dimethyl fumarate, or DMF, for the treatment of multiple sclerosis patients, or MS. Since the Company's founding in 2005, it has worked to advance unique formulations of DMF, an immune modulator, as a therapeutic to improve the health and well-being of patients with immune disorders including MS. FP187, the Company's clinical candidate, is a DMF formulation that employs both matrix and delayed release technologies to control drug release which the Company plans to advance for the treatment of relapsing remitting MS, or RRMS, and other immune disorders, such as psoriasis.

Section 1 – Basis of Preparation

1.1 Accounting policies

Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

The consolidated financial statements have been prepared on a historical cost basis, except for derivative financial instruments (net settlement obligation to shareholder warrants) that have been measured at fair value. The consolidated financial statements are presented in U.S. Dollars, or USD, and all values are rounded to the nearest thousand (USD'000), except when otherwise indicated.

First-time adoption of IFRS

These consolidated financial statements, for the years ended December 31, 2013 and 2012, are the first consolidated financial statements the Company has prepared in accordance with IFRS as issued by the IASB. The opening consolidated statement of financial position was prepared as of January 1, 2012 (the date of transition to IFRS). For periods up to and including the year ended December 31, 2012, the Company and its Subsidiary prepared their separate financial statements in accordance with Danish and German generally accepted accounting principle (Danish GAAP and German GAAP, respectively). However, no reconciliation from Danish GAAP (the prior reporting standards of the Company) to IFRS is presented because only separate financial statements of the Company were presented.

Exemptions applied

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS.

The Group has applied the following exemptions:

- Currency translation of foreign operations was reset to zero on January 1, 2012. Going forward, amounts recognized on translation of foreign operations are recorded in a separate foreign currency translation reserve in equity.

Estimates

The estimates used by the Group to present these amounts in accordance with IFRS reflect conditions as of January 1, 2012 (the date of transition to IFRS), at the transaction dates, and as of December 31, 2013 and December 31, 2012.

The estimates at January 1, 2012 and at December 31, 2012 are consistent with those made for the same dates in accordance with Danish and German GAAP respectively (after adjustments to reflect any differences in accounting policies), except for estimates regarding share-based payment transactions and net settlement obligation to shareholders warrants where application of Danish and German GAAP did not require estimation.

Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group as of December 31, 2013 and 2012 and January 1, 2012 and for the years ended December 31, 2013 and 2012.

Subsidiaries are consolidated from the date of acquisition, being the date on which the Group obtains control, and continue to be consolidated until the date when such control ceases. The financial statements of the subsidiaries are prepared for the same reporting period as the parent company, using consistent accounting policies. All intra-group balances, transactions, unrealized gains and losses resulting from intra-group transactions and dividends are eliminated in full.

Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the subsidiary.

Foreign currencies

The Company's consolidated financial statements are presented in USD which is not the functional currency of the parent company. The Group has elected USD as the presentation currency due to the fact that the Company plans to list securities on the NASDAQ Global Market, or NASDAQ.

For each entity the Group determines the functional currency and items included in the financial statements of each entity are measured using the functional currency.

Transactions and balances

Transactions in foreign currencies are initially recorded by the Group entities in their respective functional currency using the spot rate at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rate at each reporting date.

Differences arising on settlement or translation of monetary items denominated in foreign currency are recognized in the statement of profit or loss within "Finance income" or "Other finance cost" as appropriate.

Translation from functional currencies to presentation currency

In the translation to the presentation currency for entities with a functional currency different from USD, the statement of comprehensive income is translated into USD at average exchange rates, and the assets and liabilities are translated at the exchange rates at the balance sheet date. Exchange differences arising from such translation are recognized directly in other comprehensive income and presented in a separate reserve in equity. The Group uses the direct method of consolidation and has elected to recycle gain or loss that arises from this method.

Share-based payments

Employees (including senior executives) of the Group and consultants providing similar services as employees receive remuneration in the form of equity settled transactions, whereby employees render services as consideration for equity instruments (warrants). The cost of these equity-settled transactions is determined by the fair value at the date when grant is made using an appropriate valuation model.

The cost is recognized as employee benefits expense (note 2.5), together with a corresponding increase in equity over the period in which the performance and/or service conditions are fulfilled. Warrants granted conditional upon the same number of warrants granted in prior periods that have not been exercised are treated as replacement warrants. The incremental value as of the replacement date is recognized as an expense over the period over which performance and/or service conditions of the replacement warrants are fulfilled.

The cumulative cost recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group's best estimate of the number of warrants that will ultimately vest.

No cost is recognized for awards that do not ultimately vest.

Other employee benefits

Short term employee benefits are primarily made up of employee salaries, which are recognized along with delivery of services.

The Group operates defined contribution plans. Contributions under those plans are recognized as an expense along with the related service costs.

Classification of Operating Expenses in the Income Statement

Research and development costs

Research and development costs primarily comprise salary and related expenses (including share-based payment expense), license costs, manufacturing costs, clinical costs, and amortization and depreciation of non-current assets, to the extent that such costs are related to the Group's development activities.

The Group's research and development activities concentrate on the development of the immunomodulatory compound dimethyl fumarate and derivatives, for applications as pharmaceutical drug product in lead areas of neurology, dermatology and oncology. Research and development costs are not eligible for capitalization and consequently expensed in the period incurred.

General and administrative costs

General and administrative costs relate to the administration of the Group, and comprise salaries, including share-based payment expense, and amortization and depreciation, to the extent such expenses are related to the administrative functions.

Government grants

Government grants received relating to research and development activities are recorded as an offset to the expense to which they relate.

Government grants are recognized where there is reasonable assurance that the grant will be received and all attached conditions will be complied with. When the grant relates to an expense item, it is recognized as a deduction in reporting the related expense on a systematic basis over the periods that the related costs, for which it is intended to compensate, are expensed. When the grant relates to an asset, it is recognized as income in equal amounts over the expected useful life of the related asset.

For more information on government grants, refer to note 2.3.

Income tax and deferred tax

Current income tax

Current income tax assets and liabilities for the current period are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted, at the reporting date in the countries where the Group operates and generates taxable income.

Management periodically evaluates positions taken in the tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes provisions where appropriate.

Deferred tax

Deferred tax is provided using the liability method on temporary differences between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes at the reporting date.

Deferred tax assets are recognized for all deductible temporary differences, the carry forward of unused tax credits and any unused tax losses to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, and the carry forward of unused tax credits and unused tax losses can be utilized.

The carrying amount of deferred tax assets is reviewed at each reporting date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred tax asset to be utilized. Unrecognized deferred tax assets are re-assessed at each

reporting date and are recognized to the extent that it has become probable that future taxable profits will allow the deferred tax asset to be recovered.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply in the year when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted at the reporting date.

Deferred tax relating to items recognized outside the profit or loss is recognized outside profit or loss. Deferred tax items are recognized in correlation to the underlying transaction either in OCI or directly in equity.

Deferred tax assets and deferred tax liabilities are offset if a legally enforceable right exists to set off current tax assets against current income tax liabilities and the deferred taxes relate to the same taxable entity and the same taxation authority.

As of 2013, the Company is subject to a joint taxation scheme with Tech Growth Invest Aps (see note 5.2.) and entities under Tech Growth Invest ApS' control. Under this Scheme, the Company will receive a refund for tax losses at the applicable corporate tax rate to the extent that they reduce the taxable income of the joint taxation Group.

Property, plant and equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and accumulated impairment losses, if any.

Depreciation is based on the residual value and is calculated on a straight-line basis over the expected useful lives of the assets, which are:

- Other fixtures and fitting, tools and equipment 3 years

Residual values, the useful life of and method of depreciation of other fixtures and fittings, tools and equipment are reviewed at least at each financial year-end.

Financial assets

Initial recognition and measurement

The Group's financial assets are classified, at initial recognition, as loans and receivables. The Group has no derivative assets, securities or other investments. All financial assets are recognized initially at fair value plus, in the case of financial assets not recorded at fair value through profit or loss, transaction costs that are attributable to the acquisition of the financial asset, if any.

Subsequent measurement

The subsequent measurement of financial assets depends on their classification.

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. After initial measurement, such financial assets are subsequently measured at amortized cost using the effective interest rate method. This category applies to cash and cash equivalents and government grants receivables.

Other receivables

Other receivables primarily comprise VAT receivables and government grants receivables. Other receivables that are not financial assets are recognized and measured at cost less any impairment losses, if any. There have been no impairment losses in the financial periods presented.

For more information on other receivables, refer to note 3.2.

Loans

Loans are initially recognized at fair value, net of transaction costs incurred, if any. Loans are subsequently measured at amortized cost using the effective interest rate method, or EIR. Gains and losses are recognized in the statement of profit or loss within other finance costs when liabilities are derecognized as well as through the EIR amortization process.

Amortized cost is calculated by taking into account any discount or premium on acquisition and fees or costs that are an integral part of the EIR.

In terms of convertible loans, the Group evaluates the terms of financial liability contracts to determine whether a contract contains an equity conversion option or a non-closely embedded derivative. Equity conversion options are separated from the liability and treated as equity. The equity component is determined as the difference between the proceeds and the fair value of the liability component.

For more information on loans, refer to note 3.3 and 4.4.

Derivative financial instruments

Derivative financial instruments comprise net settlement obligation to shareholder warrants.

Shareholder warrants issued by the Group with shares of the Parent as the underlying security are classified as derivative financial instruments if the holder has settlement alternatives and not all of them will result in equity classification. Such derivatives are initially measured at fair value and are subsequently remeasured at their fair value. Gains and losses are recognized in the statement of profit and loss and classified as financial items. These derivatives are classified as liabilities as they are exercisable at any time. For more information on derivative financial instruments, refer to note 4.4.

Trade payables

Trade payables are initially recognized at fair value and subsequently measured at amortized cost using the effective interest method.

Cash and cash equivalents

Cash and cash-equivalents comprise cash at banks and in hand.

Consolidated statement of cash flow

The Consolidated Statement of Cash Flows is presented using the indirect method. The Consolidated Statement of Cash Flows shows cash flows used in operating activities, cash flows used in investing activities, cash flows from financing activities, and the Group's cash and cash equivalents at the beginning and end of the year.

Cash flows used in operating activities is comprised of net profit or loss for the year adjusted for non-cash items, such as share based payment expense, fair value revaluations of shareholder warrants, depreciations, paid financial items, corporate tax paid, and change in working capital.

Cash flows used in investing activities is comprised of payments relating to property, plant and equipment.

Cash flows from financing activities is comprised of proceeds from borrowings, such as interest-bearing convertible loans, and proceeds from share issuances and related transaction costs.

1.2 Significant accounting judgments, estimates and assumptions

The preparation of the consolidated financial statements requires management to make judgments, estimates and assumptions that affect the reported amounts of income, expenses, assets and liabilities, as well as the accompanying disclosures. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the asset or liability affected in future periods.

Judgments made in applying accounting policies

In the process of applying the Group's accounting policies, management has made the following judgments, which have the most significant effect on the amounts recognized in the consolidated financial statements:

Assumption and uncertainties related to going concern	Note 2.1
Government grants	Note 2.3

These areas involving a high degree of judgment that are significant to the financial statements are described in more detail in the related notes.

Estimates and assumptions

The key assumptions concerning the future and other key sources of estimation uncertainty at the reporting date, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year, are described below. The Group based its assumptions and estimates on information available when the consolidated financial statements were prepared. Existing circumstances arising beyond the control of the Group are reflected in the assumptions when they occur.

Management has determined that the following items are involved with a high degree of estimation uncertainty.

Valuation of share-based payment	Note 2.5
Deferred tax assets	Note 2.6
Valuation of net settlement obligation to shareholder warrants	Note 4.4

These areas involving a high degree of estimation that are significant to the financial statements are described in more detail in the related notes.

1.3 Standards issued but not yet effective

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning after January 1, 2014, and have not been applied in preparing these consolidated financial statements. The Group intends to adopt standards relevant to the Group, when they become effective.

Standards issued but not yet effective:

Annual Improvements 2010-2012 cycle: Introduces minor amendments to IFRS 2 Share-based Payment, IFRS 3 Business Combinations, IFRS 8 Operating segments, IFRS 13 Fair Value Measurement, IAS 16 Property, plant and equipment, IAS 24 Related party disclosures, IAS 38 Intangible assets. None of these amendments are expected to have effect on the consolidated financial statements of the Group.

Annual Improvements 2011-2013 cycle: Introduces minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 13 Fair Value Measurement. None of these amendments are expected to have effect on the consolidated financial statements of the Group.

IFRS 9 Financial instruments: Classification and Measurement. Effective date not yet determined. The adoption of the first phase of IFRS 9 might have an effect on the classification and measurement of the Group's financial assets and financial liabilities. The Group will quantify the effect in conjunction with the other phases, when the final standard including all phases is issued.

Section 2 – Results for the Year

2.1 Assumptions and uncertainties related to going concern

The Group has a history of net losses, which were \$15,696 thousand and \$22,479 thousand for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, the Group had an accumulated deficit of \$51,913 thousand.

The Group's ability to continue to operate is dependent upon raising additional funds to finance its ongoing activities. According to Management's estimates, based on the Group's budget, they have resources to fund its operations until April 2014. If the Group is not successful in obtaining additional capital resources to maintain its operational activities, there is substantial doubt that the Group will be able to continue its activity from April until December 31, 2014. The Group is contemplating an initial public offering of its securities on NASDAQ Global Market, for the purpose of raising capital to finance its operations. Furthermore, the Group anticipates entering into a bridge financing.

Subsequent to December 31, 2013, the Group obtained additional financing in the amount of \$1,972 thousand from issuance of 8,841 Class B shares. Furthermore, the interest-bearing convertible loan with a principal of \$2,566 thousand has been settled and the investor warrants have been exercised in a single transaction under which 138,010 Class A shares were issued at a consideration of \$4.8 thousand and cancellation of the interest-bearing convertible bond. The matters are described in more detail in note 5.3.

There are no assurances, however, that the Group will be successful in obtaining an adequate level of financing needed for the long-term development and commercialization of its products. The financial statements do not include any adjustments with respect to the carrying amounts of assets and liabilities and their classification that might be necessary should the Company be unable to continue as a going concern. Should neither the bridge financing nor proceeds from listing its securities materialize or occur as expected, the Board will need to consider alternative arrangements and such arrangements could have a potentially significant negative impact on the current net asset value of the Group.

Although bridge financing and proceeds from listing its securities have not yet been obtained to the Group, the Company's board of directors believes it is likely that adequate funding from the anticipated bridge financing and proceeds from listing its securities will be received and such that the Group consequently will have sufficient liquidity to fund the Group's conduct its activities for at least the next 12 months. On this basis the Board continues to view the Group as a going concern.

2.2 Segment information

For management purposes, the Group is managed and operated as one business unit which is reflected in the organizational structure and internal reporting. The Company's chief operating decision maker, its CEO, manages the Group's operations on an integrated basis for the purpose of allocating resources and evaluating performance. No separate lines of business or separate business entities have been identified with respect to any product candidate or geographical market and no segment information is currently disclosed in the Group's internal reporting.

Accordingly, it has been concluded that it is not relevant to include segment disclosures in the financial statements as the group business activities are not organized into business units, products or geographical areas.

The total non-current assets other than financial instruments and deferred tax assets located in Denmark is \$2 thousand and the total located in Germany is \$3 thousand. In 2012, the total non-current assets other than financial instruments and deferred tax assets located in Denmark was \$4 thousand, and the total located in Germany was \$2 thousand.

2.3 Government grants

For the year ended December 31, 2012, the Group received \$1,007 thousand as compensation for development costs incurred in 2012. The grant has been offset against costs incurred. No grants were received in 2013.

Judgment made on applying accounting policies

As part of the projects for the development of new or innovative products and procedures in the Free State of Saxony, the Sächsische Aufbaubank – Förderbank (“SAB”) granted the Subsidiary, a grant of 50.48% of certain development costs it incurs. The Subsidiary received an aggregate grant of \$5,236 thousand for the period from March 1, 2007 through December 31, 2012. In the event that a production site has not been established in Saxony by May 31, 2017, the grant shall be repaid to SAB in an amount up to the revenue arising from sales of the product developed or from sale of the intellectual property rights associated with the product development, up to a maximum of the grant amount, plus interest. The maximum of the grant amount, including interests, amounted to \$5,473 thousand as at December 31, 2013 and \$5,236 thousand as at December 31, 2012.

It is Management’s judgment that the purpose of the grant has primarily been to subsidize project development and not to ensure establishment of production facilities in Saxony. On this basis, Management has determined that it is appropriate to treat the grant as reimbursement of costs incurred rather than a capital grant. Consequently, the grant has been recognized as a deduction in reporting the related expense in prior years and not as deferred income. Please refer to note 5.1.

2.4 Staff Costs

	Year ended December 31,	
	2013	2012
	USD'000	USD'000
Wages and salaries	579	375
Social security costs	101	48
Pension costs	0	7
Share-based payment (note 2.5)	579	458
Total	1,259	888

Staff costs are included in the income statement as follows:

Research and development costs	1,014	731
General and administrative costs	245	157
Total	1,259	888

Compensation to key management personnel of the Group

Short-term employee benefits	325	279
Share-based payment transactions	164	177
Total compensation paid to key management personnel	489	456

The amounts disclosed in the table above are the amounts recognized as an expense during the reporting period related to key management personnel. Key management consists of executive officers and the Company's board of directors.

2.5 Share-based payment

The Group has entered into various share-based payment arrangements through the grant of warrants. The warrants are conditional upon continued employment, and exercise of some of the replacement warrants are additionally subject to a specified exit event occurring within a specified time frame. The vesting period for replacement warrants is approximately 1 year. The warrants which are not granted in replacement for unvested warrants are conditional upon continued employment of 1 -2 years.

In 2013, key management personnel were granted 18,719 warrants, all of which were granted as replacements for unexercised warrants that had been granted in previous years. The exercise price is \$28 per share. Employees and consultants were granted 52,592 warrants, of which 39,592 were granted as replacement for unexercised warrants that had been granted in prior years, with an exercise price ranging between \$13 and \$28 per share. The exercise price for 6,000 warrant issued other than as replacements for previously granted warrants is \$13 per share and the exercise price for the remaining 7,000 warrants is \$170 per share. The cost of warrants granted in the year ended December 31, 2013 is \$579 thousand.

In 2012, key management personnel were granted 28,079 warrants and employees and consultants were granted 34,452 warrants, each with an exercise price of \$26 per share. The warrants are conditional upon continued employment with respect of employees and continued delivery of service with respect of consultants and vest over a period of between 15 and 22 months. The cost of warrants granted in the year ended December 31, 2012 is \$458 thousand.

No warrants were cancelled in either 2013 or 2012. 58,311 warrants expired in the year ended December 31, 2013 and have been replaced by warrants with the same exercise price; 19,326 warrants expired in 2013 without replacement. No warrants expired in the year ended December 31, 2012.

Movements in the year

The following table illustrates the number (no.) and weighted average exercise prices (WAEP) of, and movements in, warrants during the year :

	Key Management personnel No.	Employees and consultants No.	Total No.	WAEP \$
Outstanding at January 1, 2012	27,463	96,628	124,091	12.7
Granted during the year	28,079	34,452	62,531	26.0
Forfeited during the year	-5,024	0	-5,024	15.3
Reclassification	-17,439	17,439	0	-
Expired during the year	0	-35,500	-35,500	12.2
Outstanding at December 31, 2012	33,079	113,019	146,098	18.9
Exercisable at December 31, 2012	12,285	41,559	53,644	
Granted during the year	18,719	52,592	71,311	35.2
Expired during the year	-18,719	-58,917	-77,636	19.7
Outstanding at December 31, 2013	33,079	106,694	139,773	27.9
Exercisable at December 31, 2013	9,281	57,664	66,945	

The weighted average remaining contractual life for the warrants outstanding is 1.3 years as at December 31, 2013. As at December 31, 2012, the weighted average remaining contractual life for warrants outstanding was 2.6 years.

The range of exercise prices for warrants outstanding at the end of the year was the following

Exercise price (USD per share)	2013	2012
	No.	No.
13	57,892	71,217
18	12,350	12,350
28	62,531	62,531
170	7,000	0
Total	139,773	146,098

The following tables list the inputs to the models used for the plan for the years ended December 31, 2013 and 2012:

	2013	2012
Dividend yield (%)	0%	0%
Expected volatility (%)	111 - 117	107 - 116
Risk-free interest rate (%)	0.0 – 0.6	-0.2 – 0.2
Expected life of warrants (years)	0.5 – 1.9	1.0 – 1.3
Share price (\$)	137	26
Model used	Black scholes	Black scholes
Basis for determination of share price	DCF-model	Past capital increases

The weighted average fair value of warrants granted during the year ended December 31, 2013 amounted to \$18.8, an increase from \$11.3, the weighted average fair value of the warrants granted during the year ended December 31, 2012. Fair value of warrants granted during the year ended December 31, 2013 amounted to \$1,340 thousand, an increase from \$703 thousand, the fair value of the warrants granted during the year ended December 31, 2012.

The expected life of the warrants is based on an expectation that holders will exercise their options on the occurrence of a listing or at vesting date subsequent to a listing of the Company and is not necessarily indicative of exercise patterns that may occur.

The expected volatility is based on peer group data and reflects the assumption that the historically volatility over a period similar to the life of the warrants is indicative of future trends, which may not necessarily be the actual outcome. The peer group consists of listed companies which Management believes are similar to the Company in respect of therapy area and stage of development.

Significant estimation uncertainty regarding share based payments

Determination of the initial fair value and subsequent compensation expenses for the Group’s employee warrants are subject to significant estimation uncertainty. In public listed entities, the fair value is calculated using option valuations model using the traded price of the shares and expected volatility supported by historical volatility of the share price.

The Company is a private entity, and its shares are governed by a shareholders’ agreement, which restricts the trading of the shares and provides different liquidation preferences rights among share classes. The share price at the date of grant has up until December 31, 2012 been established by assuming that the Group will be subject to a trade sale at a price which is equivalent to the price paid in the previous finance round. In 2013, the Company issued Class B share with preferential rights. The warrants issued in 2013 give the holders right to subscribe for Class A shares, and it is not possible to establish a price at which Class A shares would have been issued at, had the Company issued Class A shares at the same time it issued Class B shares. Consequently, for the years ended December 31, 2013 and 2012, the share price was established through the estimation of fair value of the Company.

Significant estimation uncertainty regarding valuation of shares

The underlying share price applied from and including the year ended December 31, 2012 has been determined by applying a discounted cash flow (DCF) model. The expected future cash flows for the two valuations are based on strategic plans up until product launch and projections for the following years. Important parameters are likelihood of product approval and commercialization, timing of product launches, market uptake, underlying prices and implications of various healthcare reforms, reimbursement assumptions, working capital and growth assumptions subsequent to the budget and strategic plan period. Budget and strategic plans build on specific commercial assessments of the business entities and the relevant products. For the valuation as of December 31, 2013 a discount rate (WACC) of 12% has been applied and for the valuation as of December 31, 2012 a discount rate (WACC) of 10.9% has been applied. For both valuations, a marketability discount of 25% has been applied.

It is not possible to determine the expected volatility of a non-public listed entity's share price as the shares are not publicly traded. Therefore, in order to use the Black-Scholes formula, the Company has estimated the fair value of its warrants by using the volatility of what Management believes to be an appropriate public listed peer group of biopharmaceutical companies.

2.6 Income tax and deferred tax

The major components of income tax expense for the year ended December 31, 2013 and 2012 are:

Consolidated statement of profit and loss

	<u>2013</u>	<u>2012</u>
	USD'000	USD'000
<i>Current income tax:</i>		
Current income tax benefit	96	0
Income tax benefit reported in the statement of profit and loss	<u>96</u>	<u>0</u>

Current income tax benefit for 2013 arises from refund under the joint taxation scheme.

2.6 Income tax and deferred tax (continued)

The tax benefit recorded for the years ended December 31, 2013 and 2012 is reconciled as follows:

	<u>2013</u>	<u>2012</u>
	USD'000	USD'000
Net loss before tax	-15,792	-22,479
At the Company's statutory income tax rate of 25% (2012: 25%)	-3,948	-5,620
<i>Adjustments:</i>		0
Non-deductible expenses for tax purposes	1,781	4,268
Effect of higher/lower tax rate in Germany	-432	-207
Non recognized deferred tax assets	2,503	1,559
At the effective income tax rate of 1% (2012: 0%)	-96	0

Deferred tax

	Consolidated statement of financial position		
	2013	2012	January 1, 2012
	USD'000	USD'000	USD'000
Tax losses carry forwards	7,984	5,489	3,947
Share-based payment	1,591	1,692	65
Other deferred taxes	-4	-4	-4
Unrecognized deferred tax assets	-9,571	-7,177	-4,008

2.6 Income tax and deferred tax (continued)

The Group offsets tax assets and liabilities if and only if it has a legally enforceable right to set off current tax assets and current tax liabilities and the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same tax authority.

The Group has the following unrecognized deductible temporary differences as of December 31, 2013 and December 31, 2012 respectively:

	Denmark			Germany		
	2013	2012	January 1, 2012	2013	2012	January 1, 2012
	USD'000	USD'000	USD'000	USD'000	USD'000	USD'000
Unused tax losses	10,546	8,279	6,216	17,794	10,756	7,518
Deductible temporary differences regarding share based payment etc.	7,215	6,750	246	-	-	-

The Danish and German tax loss carry forwards have no expiry date. The tax loss carry forward can however only reduce positive taxable income for a year in excess of \$1,400 thousand by 60%. Other deductible temporary differences are not subject to any restrictions.

As of January 19, 2013, the Company became part of a tax group with Tech Growth Invest ApS and its subsidiaries. Under the shareholders' agreement and applicable provisions of the Danish taxation law, the Company will be entitled to obtain refunds at the prevailing tax rate from other entities within the joint taxation scheme who can utilize tax losses. The estimated refund for 2013 amounts to \$96 thousand and is included in the tax benefit line item.

Significant accounting judgments, estimates and assumptions

The Group recognizes deferred tax assets, including the tax base of tax loss carry-forwards, if Management assesses that these tax assets can be offset against positive taxable income within a foreseeable future. Significant management judgment is required to determine the amount of deferred tax assets that can be recognized, based upon the likely timing and the level of future taxable profits together with future tax planning strategies. This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

The creation and development of therapeutic products within the biopharmaceutical industry – such as the Company's product candidate FP187 (dimethyl fumarate) – is subject to considerable risks and uncertainties. Since its inception, the Company has reported significant losses, and as a consequence, the Group has unused tax losses.

Management has concluded that deferred tax assets should not be recognized as of December 31, 2013 or at December 31, 2012, in accordance with IAS 12, "Income Taxes." The tax assets are currently not deemed to meet the criteria for recognition as management is not able to provide any convincing positive evidence that deferred tax assets should be recognized.

Tax uncertainties

In 2010, the Company acquired rights related to the development of the Group's product candidate, FP187, from Aditech. Danish law requires the Company to calculate the net present value of the future payments to be made to Aditech as remuneration for the rights acquired. The net present value is the basis for the amortization of such intangibles, which may be amortized over a period of 7 years beginning with the year of purchase. The Company did not calculate the net present value of the future payments in connection with the acquisition of the rights related to FP187 and the Company has not taken any such amortization deductions as of this date. The Company is currently working with Danish tax advisors to adjust the Danish tax returns as required. Although the Company does not anticipate any material tax liabilities will result from any such adjustments, there can be no assurances there will be no additional tax liabilities or that any additional liabilities will not be material.

2.7 Loss per share

The following reflects the net loss and share data used in the basic net loss per share computations:

	<u>2013</u>	<u>2012</u>
	USD'000	USD'000
Net loss	-15,696	-22,479
Of which attributable to holders of Class B shares	<u>-458</u>	<u>0</u>
Net loss attributable to ordinary equity holders of the parent for basic earnings	-15,238	-22,479
Weighted average number of ordinary shares for basic earnings per share	1,599	1,577
Net loss per share	-9.53	-14.25

Basic loss per share amounts are calculated by dividing the net loss for the year attributable to ordinary equity holders of the parent company by the weighted average number of ordinary shares outstanding during the year. Due to the fact that the Group has incurred losses for 2013 and 2012, potential shares related to warrants have no dilutive effect. Hence, basic and diluted loss per share is the same.

As described in note 4.1, before any distribution of dividends is made to any other shareholder of the Company, the Class B shareholders shall receive a specified amount of preference dividend in case of an Exit event which is an event whereby all or materially all of the value of the Company is realized in consideration for cash or liquid securities.

Due to the fact that the Class B shares have an absolute dividend preference and not a perpetual cumulative dividend preference, a loss for an accounting period is allocated pro rata to Class A shares and Class B shares.

Section 3 – Operating Assets and Liabilities

3.1 Property, plant and equipment

	Other fixtures and fitting, tools and equip- ment	Total
	USD'000	USD'000
Cost at January 1, 2012	13	13
Additions	6	6
At December 31, 2012	19	19
Additions	3	3
Disposals	-5	-5
At December 31, 2013	17	17
Depreciation and impairment		
At January 1, 2012	-10	-10
Depreciation charge for the year	-2	-2
At December 31, 2012	-12	-12
Depreciation charge for the year	-4	-4
Disposals	4	4
At December 31, 2013	-12	12
Net book value		
At December 31, 2013	5	5
At December 31, 2012	7	7
At January 1, 2012	3	3
Useful lives	3 years	

All depreciation for the years ended December 31, 2013 and 2012 relate to research and development costs.

3.2 Other receivables (current)

	<u>2013</u>	<u>2012</u>	<u>January 1,</u>
	USD'000	USD'000	2012
			USD'000
Government grant receivable	0	0	985
Other receivables	332	109	115
Total	<u>332</u>	<u>109</u>	<u>1,100</u>

Other receivables comprise VAT receivables and similar receivables.

3.3 Trade and other payables (current)

	<u>2013</u>	<u>2012</u>	<u>January 1,</u>
	USD'000	USD'000	2012
			USD'000
Trade payables	1,095	593	191
Other payables	182	157	98
Total	<u>1,277</u>	<u>750</u>	<u>289</u>

For explanations on the Group's credit risk management processes, refer to note 4.2 – Financial risk factors

Section 4 – Capital Structure and Financial Risk and Related Items

4.1 Equity and Capital Management

Share capital

The Company has issued two classes of equity as of December 31, 2013. The number of shares issued and fully paid and related changes in the capital are as follows:

	Class A shares	Class B shares
January 1, 2012	1,526,912	-
Capital increase for cash	71,618	-
December 31, 2012	1,598,530	-
Capital increase for cash	-	37,874
Conversion of interest-bearing convertible loans	-	10,136
December 31, 2013	1,598,530	48,010

The issuance price per Class B share in 2013 was \$210. The proceeds received pursuant to the issuance of 37,874 Class B shares for cash in 2013 amounted to an aggregate of \$7,951 thousand. The issuance price per Class A share in 2012 was \$26. The proceeds received pursuant to the issuance of Class A shares in 2012 amounted to an aggregate of \$1,864 thousand.

Each Class A share and Class B share has a nominal value of \$0.18. Each Class A share carries one vote and each Class B share carries 875 votes.

Before any distribution of dividends is made to any other shareholder of the Company, the Class B shareholders shall receive preference dividend in case of an Exit event which is an event whereby all or materially all of the value of the Company is realized in consideration for cash or liquid securities. An Exit may be carried out in a variety of ways and shall include, among others:

- (i) an initial public offering of the shares in the Company;
- (ii) a trade sale of the shares in the Company's to a bona fide third-party;
- (iii) the entering into of a partnership or joint venture agreement stipulating a future, unconditioned acquisition by the partner of the Company;
- (iv) a merger whereby the Company is the discontinuing entity,
- (v) a sale of the Company's activities, including a sale of all or a material part of the Company's assets or all or a material part of the Company's intellectual property rights;
- (vi) licensing of all or a material part of the intellectual property rights of the Company in a way, which can be considered equal to an Exit; or
- (vii) a combination of the above.

The preference dividend is calculated on the basis of the capital paid in by the Class B shareholders, \$10,448 thousand and is determined as follows:

- 273% if an Exit event takes place no later than December 31, 2014
- 310% if an Exit event takes place between January 1, and June 30, 2015
- 328% if an Exit event takes place between July 1, and December 31, 2015
- 364% if an Exit event takes place between January 1, and June 30, 2016
- 382% if an Exit event takes place between July 1, and December 31, 2016
- Additional 30 percentage points per commenced calendar year after December 31, 2016.

Any dividend in excess of the above is distributed pro rata on the basis of their respective nominal shareholdings in the Company.

Equity is classified into the following reserves:

- Share capital: The nominal amount of issued capital
- Share premium: Paid in share premium on capital increases less issuance costs
- Foreign currency translation reserve: The cumulative amount of translation of the Group entities financial statements from the respective functional currencies to the Group's presentation currency
- 364% if an Exit event takes place between January 1, and June 30, 2016

Dividend distribution is based on the separate financial statements of the parent company. We have never paid or declared any cash dividends on our shares and we do not anticipate paying any cash dividends in the foreseeable future.

Capital Management

For the purpose of the Group's capital management, capital includes issued capital, share premium and all other equity reserves attributable to the equity holders of the parent. The primary objective of the Group's capital management is to maximize the shareholder value.

The board of directors' policy is to maintain a strong capital base so as to maintain investor, creditor and market confidence, and a continuous advancement of the Group's product pipeline and business in general.

For a further discussion on the adequacy of the Group's current funding and assumptions for going concern, refer to note 2.1.

4.2 Financial risk factors

The Group is exposed to a variety of financial risks: market risk (including foreign exchange risk and interest rate risk), credit risk and liquidity risk.

The Group is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the U.S. dollars (USD), British pound sterling (GBP) and the Euro (EUR).

Market risk

Foreign currency risk

The Company's functional currency is the Danish Kroner, and the Subsidiary's functional currency is the Euro. The Company anticipates that a substantial portion of any revenue earned as sale of goods and royalty payments following the successful commercialization of FP187 will be denominated in either USD or Euro. The Group's expenses to date have been largely denominated in GBP, USD, DKK and Euro.

In accordance with IFRS, at period end all of the Group's assets and liabilities denominated in foreign currencies are recorded in the Company's financial statements in DKK and in the Subsidiary's financial statements into Euro using exchange rates in effect at the balance sheet date. During the year, the transactions in foreign currencies are recorded in DKK and Euro respectively, at the applicable exchange rates on the date of the relevant transactions.

The Group does not believe there is currently a need to enter into specific contracts to reduce the exposure to changes in foreign exchange rates, such as by entering into options or forward contracts. The Group may in the future consider using forward contracts to cover future revenue and expenses.

As of December 31, 2013 and 2012, the impact on the Group's statement of profit or loss of likely changes in the USD and GBP exchange rates against the Group's functional currencies, DKK and EUR, would be as follows (USD '000).

Currency	Likely change	2013 USD'000	2012 USD'000
USD	+/-10%	-21/+21	-14/+14
GBP	+/- 10%	-62/+62	-1/+1

Interest rate risk

During 2013 and 2012, our borrowings were denominated in DKK. Due to the fact that the borrowings bear fixed interest and the limited cash position, a change in the interest rates would not have had any material impact on net loss.

Credit Risk

The management manages credit risk on a group basis.

Our cash and cash equivalents are invested primarily in saving and deposit accounts with original maturities of three months or less. Saving and deposit accounts generate a small amount of interest income. For banks and financial institutions, only independently rated parties with a minimum rating of 'A' are accepted at the beginning of the term.

Liquidity Risk

Historically, the Group has financed its operations through private placements of equity securities, grants from governmental bodies and convertible loans. To date, the Group has not generated any revenues from product sales. Based on the current strategic plans, the Group does not expect to generate significant royalty or product revenues unless and until marketing approval for, and commercialization of, FP187. The Group believes that the net proceeds from the contemplated initial public offering (IPO), together with a bridge financing the Company expects to enter into, along with the existing cash and cash equivalents, will enable the Group to fund its operating expenses and capital expenditure requirements for at least the next 24 months. The management has based this estimate on assumptions that may prove to be wrong, and the Group could use our capital resources sooner than currently expect.

As of December 31, 2013, the Group's borrowing consisted of an interest-bearing convertible loan granted by a current shareholder with a principal of DKK 13,775 thousand (\$2,513 thousand) falling due on October 31, 2018. The loan bears annual interest of 20%. The loan is mandatorily convertible on the occurrence of a financing round in which a third-party participates at the exercise price equal to the price the shares are issued at. Further, the holder has an option to convert the loan into Class B shares at a fixed conversion price of DKK 1,177 (\$223) per share at any time until maturity. The holder has a par value put option which is exercisable only if the holder exercises the 138,010 warrants described in note 4.4 on a gross settlement basis. Consequently, the Company does not have an unconditional right to defer settlement beyond 1 year, and consequently, the loan is classified as a current liability.

As described in note 5.3., the holder exercised the put option and exercised the warrants after the balance sheet date.

As of December 31, 2012, the Group's borrowing consisted of an interest-bearing convertible loan granted by a current shareholder with a principal of DKK 11,882 thousand (\$2,100 thousand) falling due on December 31, 2015. The loan bears annual interest of 10%. The loan is mandatorily convertible on the occurrence of a financing round in which a third-party participates at the exercise price equal to the price the shares are issued at. The loan note including accrued interest amounting to \$2,108 thousand was converted into 10,136 Class B shares on January 18, 2013.

The table below summarizes the maturity profile of the above financial liabilities based on contractual undiscounted cash flows.

	<u>2013</u>	<u>2012</u>	<u>January 1,</u> <u>2012</u>
	USD'000	USD'000	USD'000
0-1 years	2,613	207	-
1-5 years	-	2,481	-
Total contractual cash flows	2,613	2,688	-

As of December 31, 2013, one of the Company's shareholders was committed to increase share capital by subscribing for 8,841 Class B shares at a subscription price of \$223 each corresponding to proceeds of \$2,800 thousand. As described in note 5.2, the Company called the capital after the balance sheet date. Further, as described above, the put right of the holder of the convertible bond as of December 31, 2013 is conditional upon the holder's gross settlement of the 138,010 warrants described in note 4.4. Consequently, the settlement of the interest-bearing convertible bond before maturity does not result in any net cash outflow.

4.3 Other finance costs

	<u>2013</u>	<u>2012</u>
	USD'000	USD'000
Interest on interest-bearing convertibles loans	75	32
Other interest and financial expenses	2	0
Exchange rate losses, net	7	3
	<u>84</u>	<u>35</u>

4.4 Financial assets and liabilities

Recognized financial instruments

The group has recognized the following categories of financial assets and liabilities:

	2013		2012		January 1, 2012	
Financial assets						
<i>Loans and receivables</i>						
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
Cash and cash equivalents	2,955	2,955	828	828	427	427
Other receivables	0	0	0	0	985	985
Total	2,955		828		1,412	
<i>Financial liabilities held at fair value through profit and loss</i>						
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
Net settlement obligations to shareholder warrant	26,124	26,124	18,370	18,370	973	973
<i>Financial liabilities at amortized cost</i>						
	Carrying amount	Fair value	Carrying amount	Fair value	Carrying amount	Fair value
Interest-bearing convertible loans	2,613	2,613	2,100	2,100	0	0
Trade payables and other payables	1,095	1,095	593	593	191	191
Total	3,078		2,693		191	

Fair value of short term payables is deemed to their carrying amount. Fair value of the convertible loans is determined on the basis of the DKK zero coupon yield curve and a credit spread reflecting the credit risk of the Parent company over the term of the loans. Fair value measurement is a level three measurement as the credit spread of the Parent company is not observable.

Financial instruments recognized at fair value are allocated to one of the following valuation hierarchy levels of IFRS 7:

Level 1: Quoted (unadjusted) prices in active markets for identical assets or liabilities. The Group does not have financial instruments allocated to this level for any of the periods presented.

Level 2: Other techniques for which all inputs that have a significant effect on the recorded fair value are observable, either directly or indirectly. The Group does not have financial instruments allocated to this level for any of the periods presented.

Level 3: Techniques that use inputs that have a significant effect on the recorded fair value that are not based on observable market data. The financial instruments that the Group has allocated to this level comprise net settlement obligations to shareholders' warrants.

Net settlement obligation to shareholder warrants

On May 31, 2011, Nordic Biotech Opportunity Fund K/S, one of the Company's shareholders was granted 138,010 warrants without pre-emption rights for the Company's other shareholders. The warrants entitle the holder to subscribe for up to 138,010 Class A shares at an exercise price of \$19. Alternatively, the warrant holder can elect to exercise the warrant by reducing of warrants and reducing the exercise price by the reduction in number of shares multiplied by the per share fair value (net in share settlement). The warrants were granted for no consideration in connection with a capital increase made by the shareholder on the same date. The warrants may be exercised immediately and expire on May 31, 2014. They are subject to anti-dilution provisions.

The warrants are classified as a derivative financial instrument due to the fact that the holder can elect net in shares settlement and are recorded within current liabilities on the statement of financial position. The fair value of the liability as of December 31, 2013 is \$26,124 thousand, an increase of the fair value of liability from \$18,370 thousand, as of December 31, 2012.

Fair value is based on unobservable input (level 3). The most significant assumptions applied in determining fair value are:

	December 31, 2013	December 31, 2012
Expected life in years	0.4	1
Expected volatility (%)	78	107
Underlying share price (USD)	208	150

Expected volatility and underlying share-price are determined as set out in section 4.4 in respect of share-based payment.

Reconciliation of fair value measurement (USD'000):

	2013	2012
	USD'000	USD'000
Carrying amount at January 1	18,370	973
Fair value adjustment recognized in financial expense	6,676	17,071
Exchange differences	1,078	326
Total	26,124	18,370

Significant estimation uncertainty regarding valuation of net settlement obligation to shareholder warrants

Determination of fair value of the net settlement obligation related to shareholder warrants is associated with significant estimation uncertainty due to the fact that the shares of the Company are not traded in an active market. Based on the estimated fair value of the shares as of December 31, 2013 and 2012 respectively, the exercise price of the warrants is significantly lower than the underlying share-price as of this date. Consequently, the share price as of December 31, 2013 and 2012 respectively has the most significant impact on determination of fair value while expected volatility and expected life of the warrants have only limited impact.

For significant estimation uncertainty regarding valuation of shares, see note 2.5.

A reasonable possible change in the below assumptions would impact the underlying share price and have the following impact on the fair value of the net settlement obligation (USD '000).

		2013		2012	
	Base case			Base case	
Probability of product launch +/- 1%	6%	6,915	-6,912	4%	-6,940
Sales price +/- 10%	*	5,044	-5,056	*	-3,732
Marketability discount +/-5%	25%	-2,037	+2,037	25%	1,349
Discount rate +/- 1%	12.0%	-4,694	5,646	10.9%	4,622

* Multiple sclerosis \$23 – 60 thousand. Psoriasis \$7-15 thousand

On an overall basis, the estimation uncertainties are impacted by the fact that Group is an emerging growth entity focused on bringing FP187 through the development and to regulatory approval and subsequent commercialization. The Group does not have a long operational history with multiple developments and have not yet taken any products to the market. The Group's expertise is around formulation and tablet technology, pre-clinical and clinical development and consequently the Group's ability to assess and evaluate future market projections and financial success may be limited compared to other companies with a longer and broader commercial history.

Probability of product launch is the combined probability for successful Phase 3 completion, sale and regulatory approval. Several different factors may impact the successful outcome of our activities leading to commercialization of FP187, including

- The successful performance of clinical trials that generate the regulatory data for the New Drug Application (NDA) and the approval may not be completed in a timely manner leading to delays, non-completion of the trial or the data may not come out as successful as expected. There may be high competition for patients to enter our trials or the required regulatory trial approvals may not come or be delayed.
- There is considerable uncertainty in the regulatory approval process. The agency reviews may bring up issues that may not be resolvable without new data or the response to such agency review and questions may delay the process or result in non-approval and materially impact the possibility for generating revenues from the product without further investment and time.

Sales price is the average annual price for treatment of one patient.

- For the future sales of our product there is considerable uncertainty with regards to price setting and reimbursement. The governments' politics varies from country to country however generally there are constraints on medication cost and the processes for the determination/negotiation of drug prices may change. Third-party payers may also use listings of approved products for certain diseases that are fully reimbursable in which the Group's products may not be included. Such actions or regulations make future sales predictions highly uncertain.

Marketability discount is a deduction in the net present value of the future cash flows due to the fact that the shares of the Company are not traded in an active market.

The discount rate is the rate applied on discounting the future cash flows to their present value.

Section 5 – Other Disclosures

5.1 Commitments and contingent liabilities

Leasing- Group as lessee

Lease contracts, where the lessor retains the significant risks and rewards associated with the ownership of the asset, are classified as operating leases.

Lease payments under operating leases are recognized in the income statement over the lease term. The total lease commitment under operating leases is \$21 thousand, relating to a lease agreement expiring in September 2014 for the rental of property. Lease payments recognized as an expense amounted to \$60 thousand in the year ended December 31, 2013 and: \$30 thousand in the year ended December 31, 2012.

Contingent liabilities

Contingent liabilities are liabilities that arose from past events but whose existence will only be confirmed by the occurrence or non-occurrence of future events that are beyond the Company's control.

A grant in total of \$5,236 thousand received as compensation for development costs incurred shall be repaid with an amount up to the revenue arising from sales of the product developed or from sale of the intellectual property rights associated with the product development if a production site has not been established in Saxony no later May 31, 2017. As of December 31, 2013, Management has not decided whether to establish production facilities in Saxony. Further, it is Management's assessment that as of December 31, 2013, there is uncertainty in respect of future revenue from the development project or alternatively proceeds from sale of the Intellectual property rights if the Company ceases development. On this basis, Management has determined that it is appropriate not to recognize a liability for the contingent repayment of the grant.

As of January 19, 2013, the Company became part of a tax group with its parent company Tech Growth Invest ApS and its subsidiaries and is jointly and severable liable for the tax liabilities in those entities. See notes 2.6 and 5.2.

5.2 Related party disclosures

As of December 31, 2013, the Company was controlled by NB FP Investment K/S. The ultimate controlling party of the Company is Florian Schönharting who controls NB FP Investment K/S through Tech Growth Invest ApS. In 2012, no party controlled the Company.

As of January 19, 2013, the Company became part of the tax group of Tech Growth Invest ApS for purposes of Danish law. The relative responsibilities of the Company and the other members of the group are set forth in the Company's shareholders' agreement. Danish law provides for joint income taxation for all Danish entities in the same tax group, with the result that losses by one entity would be offset by gains by another. However, Danish law requires entities in the same tax group to pay each other for the use of each other's tax losses. Therefore, any use of the Group's losses by other members of the Tech Growth tax group will result in compensation to the Company. All members of a Danish tax group are jointly and severally liable for the group's Danish tax liabilities. Refer to note 2.6.

The following table provides the total amount of transactions that have been entered into with related parties for the relevant year.

	<u>2013</u> USD'000	<u>2012</u> USD'000
Interest paid	75	32
Purchase of services	62	30
Amounts owed to related parties	2,613	2,100
Amounts owed by related parties	6	5

Terms and conditions of transactions with related parties

The sales to and purchases from related parties are made at terms equivalent to those that prevail in arm's length transactions. Outstanding balances at the year-end are unsecured and interest free. There have been no guarantees provided or received for any related party receivables or payables. For the years ended December 31, 2013 and 2012, the Group has not recorded any impairment of receivables relating to amounts owed by related parties.

Transactions with key management

The Group has not granted any loans, guarantees, or other commitments to or on behalf of any of the members of the board of directors or key management personnel.

Other than the remuneration including share-based payment relating to key management personnel described in note 2.4 and 2.5, no other significant transactions have taken place with key management personnel during 2013 and 2012.

Net settlement obligations to shareholder warrants

As of December 31, 2013 and 2012, 138,010 warrants were held by Nordic Biotech Opportunity Fund K/S which had significant influence due to share ownership. The warrants are classified as derivative financial instruments with fair value gains and losses recognized in profit or loss. Refer to note 4.4 for details in respect of the carrying amount and fair value gains/losses.

Capital increases

The capital increase in 2012 discussed in note 4.1. was subscribed by parties who through share ownership had significant influence over the Company. Of the capital increases in 2013, 37,874 shares were subscribed by NB FP Investment K/S which obtained control of the Company on subscribing for those shares. The remaining 10,136 shares were subscribed through conversion of an interest-bearing convertible loan by Nordic Biotech Opportunity Fund K/S who has significant influence.

Patent transfer agreement between Aditech Pharma AG and the Company

Aditech Pharma AG is considered to be a related party of the Company due to control over Aditech Pharma AG held by one of the Company's major shareholders, Nordic Biotech K/S.

In 2004, a private Swedish company Aditech Pharma AB (collectively with its successor-in-interest, a Swiss company Aditech Pharma AG, or Aditech), controlled by Nordic Biotech Advisors, an affiliate of one of the Company's largest shareholders, began developing and filing patents for, among other things, an innovative delayed and controlled release formulation for DMF. In 2005 the Group entered into a patent license agreement with Aditech to license this patent family from Aditech, and in 2010 the Group acquired this patent family from Aditech pursuant to a patent transfer agreement. Under the Group's agreements with Aditech, the Group obtained, among other things, Aditech's patents and associated know-how related to DMF formulations and delivery systems, subject to both diligence obligations and minimum annual research and development expenditure (€1,000 thousand per year) related to the continued development of DMF formulations on the part of the Group (with an option for Aditech to receive back, for no consideration, all of the Group's DMF related assets should it fail to satisfy these obligations), as well as a payment by the Group to Aditech of up to 2% of net sales generated from the Group's DMF products and processes. Further, the Group's agreement with Aditech gives Aditech a 90-day right of first offer to acquire non-DMF related intellectual property assets that the Group might choose to sell.

5.3 Events after the reporting period

On March 13, 2014, the Company exercised its right to call for issuance of 8,841 Class B shares at an exercise price of \$223 per share resulting in proceeds of \$1,972 thousand.

On March 17, 2014, Nordic Biotech Opportunity Fund K/S converted its shareholder loan with a principal value of \$2,566 thousand into 137,750 Class A shares by way of which the principal amount outstanding under the loan was offset against the exercise price of an aggregate of 137,750 warrants to purchase Class A shares, at an exercise price of DKK 100 per share, and subscribed for an additional 260 Class A shares by way of exercise of 260 warrants to purchase Class A shares at a subscription price of DKK 100 per share.

As described in note 2.1, the Group initiated in 2014 the process of listing its securities on the NASDAQ Global Market (the IPO). In connection with such process, the Group has incurred significant costs. It is anticipated that such costs will be financed through a bridge financing that the Group expects to enter into prior to consummation of the IPO.

shares



Ordinary Shares

Prospectus

Leerink Partners

, 2014

We have not authorized anyone to provide any information other than that contained in this Prospectus or in any free **writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility** for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters have not authorized any other person to provide you with different or additional information. Neither we nor the underwriters are making an offer to sell the ordinary shares in any state or jurisdiction where the offer or sale is not permitted. This offering is being made in the United States and elsewhere solely on the basis of the information contained in this Prospectus. You should assume that the information appearing in this Prospectus is accurate only as of the date on the front cover of this Prospectus, regardless of the time of delivery of this Prospectus or any sale of the ordinary shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this Prospectus.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the ordinary shares or possession or distribution of this Prospectus in that jurisdiction. Persons who come into possession of this Prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of this Prospectus applicable to that jurisdiction.

Until , 2014, all dealers that buy, sell or trade in our ordinary shares, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

Part II—Information not required in the prospectus

Item 6. Indemnification of directors and officers

Our Articles of Association does not currently provide for indemnification of our officers or directors.

We intend to enter into indemnification agreements with each of our officers and directors upon or prior to the consummation of this offering.

Item 7. Recent sales of unregistered securities

Sales of Class A and Class B shares

On May 31, 2011, we issued and sold an aggregate of 69,005 Class A shares to Nordic Biotech Opportunity Fund K/S, or NBOF, for an aggregate purchase price of DKK 6.9 million.

On March 8, 2012, we issued and sold an aggregate of 34,673 Class A shares to NBOF for an aggregate purchase price of DKK 5.2 million to NBOF, and an aggregate of 15,460 Class A shares to BML Healthcare I, L.P., or BML, for an aggregate purchase price of DKK 2.3 million.

On July 24, 2012, we issued and sold an aggregate of 14,860 Class A shares to NBOF for an aggregate purchase price of DKK 2.2 million, and an aggregate of 6,625 Class A shares to BML for an aggregate purchase price of DKK 993,750.

On January 18, 2013, we issued and sold an aggregate of 10,136 Class B shares to NBOF for an aggregate purchase price of DKK 11.9 million.

We and each of our shareholders as of the date hereof is party to an Investment Agreement dated January 19, 2013, pursuant to which NB FP Investment K/S, or NBFP, agreed to subscribe for up to 46,715 Class B shares, at our request, at a subscription price of DKK 1,177.35 per share. On March 13, 2013, July 3, 2013, November 4, 2013 and March 17, 2014, NBFP subscribed for an aggregate of 12,250, 12,670, 12,965, and 8,841 Class B shares, for an aggregate purchase price of DKK 54,999,905.

All of the sales described above were made in reliance upon the exemption from registration under Section 4(2) of the Securities Act. We have used the proceeds from this offering for research and development and general corporate purposes.

Issuances of Warrants

The table below summarizes our warrants issued within the past three years. The grant of the warrants and the issuance of Class A shares upon the exercise of options described in the table below were or will be made pursuant to Section 4(2) of the Securities Act.

<u>Date</u>	<u>Number of Warrants Granted</u>	<u>Exercise Price of Warrants</u>
May 31, 2011	138,010	DKK 100
September 3, 2012	48,671	DKK 150
December 8, 2012	9,360	DKK 150
December 18, 2012	4,500	DKK 150
June 17, 2013	17,500	DKK 70.061
August 22, 2013	7,000	DKK 920.36
October 4, 2013	9,372	DKK 70.061
October 4, 2013	37,439	DKK 150

Item 8. Exhibits

(a) The following documents are filed as part of this Registration Statement:

- 1.1* Form of Underwriting Agreement.
- 3.1* Form of Articles of Association of Forward Pharma A/S.
- 3.2* Articles of Association of Forward Pharma A/S dated March 17, 2014.
- 4.1* Form of Registration Rights Agreement.
- 5.1* Opinion of Nielsen Nørager, counsel of Forward Pharma A/S, as to the validity of the ordinary shares.
- 8.1* Opinion of Nielsen Nørager, counsel of Forward Pharma A/S, as to certain tax matters.
- 8.2* Opinion of Dechert LLP, counsel of Forward Pharma A/S, as to U.S. tax matters.
- 10.1* Patent License Agreement dated July 1, 2005 between Forward Pharma A/S and Aditech Pharma A/B.
- 10.2* Form of Director and Officer Indemnification Agreement.
- 21.1 List of subsidiaries.
- 23.1* Consent of Ernst & Young P/S.
- 23.2* Consent of Nielsen Nørager, counsel of Forward Pharma A/S (included in Exhibit 5.1).
- 23.3* Consent of Nielsen Nørager, counsel of Forward Pharma A/S (included in Exhibit 8.1).
- 23.4* Consent of Nielsen Nørager, counsel of Forward Pharma A/S (included in Exhibit 8.2).

* To be filed by amendment.

(b) Financial Statements Schedules

None.

Item 9. Undertakings

The undersigned hereby undertakes:

(a) The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant

has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Signatures

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Copenhagen, Denmark on _____, 2014.

FORWARD PHARMA A/S

By:

Name: Peder Møller Andersen
Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on _____, 2014, in the capacities indicated:

Name	Title
_____ Peder Møller Andersen	Chief Executive Officer (principal executive officer)
_____ Florian Schönharting	Chief Financial Officer (principal financial officer)
_____ J. Kevin Buchi	Director (Chairman)
_____ Torsten Goesch	Director
	Director

Signature of Authorized U.S. Representative of Registrant

Pursuant to the requirements of the Securities Act of 1933, the undersigned, the duly authorized representative in the United States of Forward Pharma A/S has signed this registration statement on _____, 2014.

FORWARD PHARMA A/S

By:

Name: Peder Møller Andersen
Title: Chief Executive Officer

Exhibit index

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- 8.2* Opinion of Dechert LLP, counsel of Forward Pharma A/S, as to U.S. tax matters.
- 10.1* Patent Transfer Agreement dated May 4, 2010 between Forward Pharma A/S and Aditech Pharma AG.
- 10.2* Form of Director and Officer Indemnification Agreement.
- 21.1 List of subsidiaries.
- 23.1* Consent of Ernst & Young P/S.
- 23.2* Consent of Nielsen Nørager, counsel of Forward Pharma A/S (included in Exhibit 5.1).
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* To be filed by amendment.

List of Subsidiaries of Forward Pharma A/S

Forward Pharma GmbH